10PTO101:D241dAPBNN3.PAM.doc:5/11/10:eff (D24-1d)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants:	Kevin A. Kelly Thomas E. Lach Ralph D. Lach Arthur W. Handshy	Group Art Unit 3764 Examiner T. M. Nguyen
Appln. No:	10/633,938	
Filed:	August 4, 2003	
For:	CHEST COMPRESSION APPARATUS FOR CARDIAC ARREST	

RESUBMISSION OF APPEAL BRIEF

The Commissioner for Patents
P.O. Box #1450
Alexandria, Virginia 22313-1450

Sir:

In light of the May 28, 2010, NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF, Applicants submit the following as their revised Appeal Brief.

In support of their appeal of the final Office action of April 21, 2009, Applicants submit the following as their Appeal Brief. The section numbers and titles correspond to those set forth in 37 C.F.R. § 41.37(c)(1).

(i) REAL PARTY IN INTEREST

The real party in interest in the application involved in the present appeal is Deca-Medics, Inc., an Ohio Corporation, located at 2844 Mt. Holyoke Road, Columbus, Ohio 43221.

(ii) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

(iii) STATUS OF CLAIMS

Claims 41 to 127, 135 to 144, 157 to 170, 183 to 197, 213 to 227, and 240 to 260 were withdrawn.

Claims 210 and 211 were cancelled.

Claims 128 to 134, 145 to 156, 171 to 182, 198 to 209, 212, and 228 to 239 were finally rejected.

Claims 128 to 134, 145 to 156, 171 to 182, 198 to 209, 212, and 228 to 239 are presently on appeal. Of these:

(a) Claims 131, 132, 148, 149, 174, 175, 201, 202, 228, and 232 were rejected under 35 U.S.C. § 112, first paragraph for failure to comply with the written description requirement;

(b) Claims 128 to 134, 145 to 156, 171 to 182, 198 to 209, 212, and 228 to 239 (i.e., all claims presently on appeal) were rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter;

(c) Claims 128 and 129 were rejected under 35 U.S.C. § 103(a) as obvious over Dedo (4,004,579) in view of Cook (3,503,388);

(d) Claims 130 to 134 and 228 to 239 were rejected under 35 U.S.C. § 103(a) as obvious over Dedo (4,004,579) in view of Cook (3,503,388) and in further view of Barkalow et al. (4,273,114);

(e) Claims 145, 146, 152 to 156, 171, 172, 178 to 182, 198, 199, 205 to 209, and 212 were rejected under 35 U.S.C. § 103(a) as obvious over Dedo (4,004,579) in view of Cook (3,503,388) and in further view of Szpur (5,407,418); and

(f) Claims 147 to 151, 173 to 177, and 200 to 204 were rejected under 35 U.S.C. § 103(a) as obvious over Dedo (4,004,579) in view of Szpur (5,407,418) and Cook (3,503,388) and in further view of Barkalow et al. (4,273,114).

(iv) STATUS OF AMENDMENTS

No amendments were filed subsequent to the final rejection of April 21, 2009.

(v) SUMMARY OF CLAIMED SUBJECT MATTER

The independent claims of the present application under appeal include Claims 128, 145, 171, 198, and 228. These read as follows:

128. A method of CPR treating patients comprising:

(A) wrapping a belt, with first and second opposite extremities, around and in contact with a substantial majority of a patient's chest near said patient's

sternum, said belt being in continuous contact with the patient's chest, including the front, sides, and a portion of the back of said patient's chest, said belt (1) extending around and being in contact with a major portion of the circumference of said chest, (2) extending around and being in contact with the front, sides and back of said chest, and (3) being substantially inelastic and flexible;

(B) fastening to a power unit said belt including any of said extremities of said belt not already fastened around said patient's chest;

(C) placing an actuator having first and second states in said first state; and

(D) with said actuator in said first state, providing power from a power supply to said power unit and moving said belt in a direction to tighten said belt around said patient's chest to perform CPR.

145. A method of CPR treating patients comprising:

(A) wrapping a belt, with first and second opposite extremities, around and in contact with a substantial majority of a patient's chest near said patient's sternum, said belt being in continuous contact with the patient's chest, including the front, sides, and a portion of the back of said patient's chest, said belt (1) extending around and being in contact with a major portion of the circumference of said chest, (2) extending around and being in contact with the front, sides and back of said chest, and (3) being substantially inelastic and flexible;

(B) fastening to an apparatus any of said extremities of said belt not already fastened to said apparatus;

(C) providing a particular signal to a powered belt tightener coupled to said belt extremities; and

(D) upon the receipt of said particular signal by said belt tightener, moving with said belt tightener, said belt extremities in directions to tighten said belt around said patient's chest to perform CPR.

171. A method of CPR treating patients comprising:

(A) wrapping a belt, with first and second opposite extremities, around and in contact with a substantial majority of a patient's chest near said patient's sternum, said belt being in continuous contact with the patient's chest, including the front, sides, and a portion of the back of said patient's chest, said belt (1) extending around and being in contact with a major portion of the circumference of said chest, (2) extending around and being in contact with the front, sides and back of said chest, and (3) being substantially inelastic and flexible;

(B) fastening to a power unit said belt including any of said extremities of said belt not already fastened around said patient's chest;

(C) conveying power from a power supply to said power unit along a cable; and

(D) when said power reaches said power unit, moving said belt in a direction to tighten said belt around said patient's chest to perform CPR.

198. A method of CPR treating patients comprising:

(A) wrapping a belt, with first and second opposite extremities, around and in contact with a substantial majority of a patient's chest near said patient's sternum, said belt being in continuous contact with the patient's chest, including the front, sides, and a portion of the back of said patient's chest, said belt (1) extending around and being in contact with a major portion of the circumference of said chest, (2) extending around and being in contact with the front, sides and back of said chest, and (3) being substantially inelastic and flexible;

(B) fastening to a power unit said belt including any of said extremities of said belt not already fastened around said patient's chest;

(C) conveying power from a power supply to said power unit along a line; and

(D) when said power reaches said power unit, moving said belt extremities in directions to tighten said belt around said patient's chest to perform CPR.

228. A method of CPR treating patients comprising:

(A) wrapping a belt around and in contact with a substantial majority of a patient's chest near said patient's sternum, said belt being in continuous contact with the patient's chest, including the front, sides, and a portion of the back of said patient's chest, said belt (1) extending around and being in contact with a major portion of the circumference of said chest, (2)

extending around and being in contact with the front, sides and back of said chest, and (3) being substantially inelastic and flexible;

(B) moving said belt in a direction to tighten said belt around said patient's chest and place said chest under compression to perform CPR;

(C) detecting when said belt has placed said patient's chest under compression; and

(D) when said belt has placed said chest under compression, inducing a defibrillating electric current through said chest.

Paragraph (A) is identical for all of these independent claims except that Claim 228 *does not include the words* "with first and second opposite extremities." Further, since these are all method claims as indicated elsewhere, the drawings, *by themselves*, may not illustrate the action of the recited step. However, the verbiage of the specification, in conjunction with the drawings, provides a detailed description of the method under consideration.

Thus, for paragraphs (A):

> The belt 40, which extends around the front, sides and back of the chest, is substantially inelastic and flexible. A plurality of indicia 50 is printed on the exposed surface of the belt 50. The belt 40 attaches to the strut 34 on one side of the chest 12, and extends around a major portion of the circumference of the chest to attach to the other strut 36. When the assemblies 16 and 18 pivot around the pivot pin 20, the belt 40 is tightened by the struts 34 and 36 to which the belt 40 attaches.
>
> Although the belt 40 is described as extending around the front, sides, and back of the chest, the belt may be made up of two or more component parts, such as a pair of belts.

> This pair of belts could extend from attachment to the struts 34 and 36, extending downwardly past the sides of the patient's chest to rigid attachment to a board which spans the width of the back of the chest. Therefore, "a belt wrapped around the chest" can be made up of two or more belt components which extend around portions of the chest circumference in combination with other rigid or flexible components. (Pages 16 and 17.)
>
> * * * * *
>
> The belt 40 extends through slots 44 formed in a backboard 42 which, *when in use*, is positioned beneath the chest 12 of the patient. The belt 40 *preferably* seats against a sliding mechanism 43 which permits sliding of the belt 40 along the length of the chest 12 for positioning of the belt 40 on the chest. (Page 18, emphases added.)
>
> * * * * *
>
> The belt 40 is then extended upwardly from the backboard 42, between the arms and chest 12, and around opposite sides of the chest to match the relaxed contour of the chest 12. The belt 40 is positioned as high on the chest 12 and as high under the underarms as possible. (Page 19.)

In particular, Figures 1, 2, 9, 10, and 16 show the belt 40 (in Figures 1 and 2), 258 (in Figure 9), 282 (in Figure 10), and 506 (in Figure 16) which has been attached in this manner. "High on the chest" places the belt over the sternum.

Paragraph (B) of Claims 128, 145, 171, and 198 recites, "(B) fastening to a power unit said belt including any of said extremities of said belt not already fastened around said patient's chest." Again, since this constitutes a method step, Figures 7 to 10 show the end result of this action. The description for these figures includes the following:

> In Fig. 7, a mechanical and electrical combination equivalent is shown diagrammatically including an actuator 200 and electric motor 202 attached to a base. The motor 202 has a pair of belt ends 206 and 208 attached to a driveshaft 210. . . .

> Fig. 8 shows still another equivalent to the present invention in a diagrammatic illustration including a hydraulic cylinder 222, fluid lines 222 and 224, and pistons 226 and 228 slidingly mounted within the cylinder 220. The belt ends 230 and 232 are mounted to the pistons 226 and 228. (Pages 29 and 30.)
>
> * * * * *
>
> It is possible to attach a power unit, such as a prime mover, to the apparatus 10 [of Figures 1 and 2] which could operate as an actuator to apply a lateral force to the arm assemblies 16 and 18 to actuate them automatically and in regular, periodic intervals. As shown in Figure 9, the power unit 254 has a cable 256 which attaches to a belt 258. . . . (Page 30.)
>
> An example of a power unit 280 applying a force which tightens a belt 282 and depresses a base 284 is shown in Fig. 10. As the rod 286 extends inwardly and outwardly of the power unit 280, the base 284 is displaced upwardly and downwardly, depressing the chest 288 as described with the preferred embodiment. Furthermore, this same mechanical motion of the rod 286 tightens and loosens the belt 282 as with the preferred embodiment. (Page 31.)

As for the apparatus 10 of Figures 1 and 2 (referenced in the second from last quoted paragraph above) the originally filed specification says:

> Once the belt extends around the struts 34 and 36, the ends of the belt 40 are folded back over onto the portion of the belt 40 contacting the chest 12 and are attached thereto by fasteners. . . .
>
> After fastening the belt 40 to the struts 34 and 36 . . . (Page 20.)

Clearly, the specification shows that the belt ends have been attached as appropriate.

Paragraphs (C) and (D) of Claim 1 recite, "(C) placing an actuator having first and second states in said first state; and (D) with said actuator in said first state, providing power from a power supply to said power unit and moving said belt in a direction to tighten said belt around said patient's chest to perform CPR." The specification says:

> In Fig. 7, a mechanical and electrical combination equivalent is shown diagrammatically including an actuator 200 and electric motor 202 attached to a base. The motor 202 has a pair of belt ends 206 and 208 attached to a driveshaft 210. Upon depression of the actuator 200, a pressure-sensitive switch 212 actuates the motor 202, rotating the driveshaft 210 and exerting a linear force on the belt ends 206 and 208 (Page 29.)
>
> Fig. 8 shows still another equivalent to the present invention in a diagrammatic illustration including a hydraulic cylinder 222, fluid lines 222 and 224, and pistons 226 and 228 slidingly mounted within the cylinder 220. The belt ends 230 and 232 are mounted to the pistons 226 and 228. Upon actuation of an actuator 234, hydraulic fluid is forced into the hydraulic cylinder 220 forcing the pistons 226 and 228 toward one another longitudinally, thereby exerting a force on the belt ends 230 and 232. . . .
>
> The actuator 234 could be attached to a central piston which compresses a fluid within a hydraulic cylinder. Upon actuation of actuator 234, the hydraulic fluid within the cylinder is compressed and is conveyed though the lines 222 and 224 and the pistons 226 and 228 are driven inwardly as described above. This embodiment is also equivalent to the preferred embodiment.
>
> It is possible to attach a power unit, such as a prime mover, to the apparatus 10 [of Figures 1 and 2] which could operate as an actuator to apply a lateral force to the arm assemblies 16 and 18 to actuate them automatically and in regular, periodic intervals. As shown in Figure 9, the power unit 254 has a cable 256 which attaches to a belt 258. The device providing a mechanical force to the belt 258 may be located in the power unit 254 and the cable 256 is then rotatingly driven or longitudinally, reciprocatingly driven to tighten and loosen the belt 258. Alternatively, the actuator which tightens and loosens the belt 258 could be located beneath the belt and the cable 256 would merely convey electrical power or fluid pressure to the actuator. The power unit 254 may use computer controls to time the application of force. (Page 30.)

Claim 145, in its paragraphs (C) and (D), says, "(C) providing a particular signal to a powered belt tightener coupled to said belt extremities; and (D) upon the receipt of said

particular signal by said belt tightener, moving with said belt tightener, said belt extremities in directions to tighten said belt around said patient's chest to perform CPR." As quoted and discussed above with reference to Figure 7, closing the actuator 200 causes the switch 212 to send a signal to the motor 202 to operate and tighten the belt ends 206 and 208. This signal could be any of the ordinary types encountered in electronics including high or low voltage, including on and off, moieties. In Figure 8, actuating the actuator 234 causes the hydraulic system such as the stated "central cylinder" to force fluid into the hydraulic cylinder 220. Figure 9 provides two ways of powering the belt 258. The power unit may provide a mechanical force to the belt along the cable 256 which is longitudinally or rotatingly driven. Alternately, the mechanical device may lie beneath the belt 258 and receive its electrical power from the cable 256 which conveys electrical power or fluid pressure. As the specification says on page 31, "The power unit 254 may use computer controls to time the application of force." Clearly, it does so by sending an appropriate, particular signal to tell the power unit to apply force in each period. This is what paragraphs (C) and (D) of Claim 145 require.

Paragraph (C) of Claim 171 requires, "conveying power from a power supply to said power unit along a cable" while the same paragraph of Claim 198 uses the word "line" for the word "cable." The discussion at the very end of the prior paragraph (for Claim 145) provides a basis for these paragraphs (C) of these two claims. Again, the particular language appears on page 30 of the specification and appears as the last full paragraph quoted above on the prior page 10 of this brief and which is set off by indentations.

Further, in Figure 7, as discussed above, power must reach the motor 202 along a cable or line in order for it to operate. In Figure 8, hydraulic power, as set forth in the quotation form page 30 of the specification given above, enters the cylinder 220 along the lines 222 and 224 to achieve CPR. This paragraph of the claims requires no more.

Paragraph (D) of the independent Claim 171 requires "when said power reaches said power unit, moving said belt in a direction to tighten said belt around said patient's chest to perform CPR." The last extensive quotation given above from pages 29 and 30 of the specification (on pages 9 and 10 of this brief) show that this belt movement constitutes the intended purpose and end result of the motion of the power unit whether it be the electric motor 202 of Figure 7, the hydraulic cylinder 220 of Figure 8, the power unit 254 of Figure 9 (or the unseen actuator which lies beneath the belt 258), or the power unit 280 of Figure 10.

Paragraph (B) of the independent Claim 228 has almost the same language. However it differs by not including the phrase "when said power reaches said power unit" which cannot require more details in the drawing and specification than Claim 171. In other words, if the specification provides a basis for the quoted language of Claim 171, it must, per force, do so as well for the more general language of Claim 228.

Paragraph (D) of the independent Claim 198 recites, "(D) when said power reaches said power unit, moving said belt *extremities in directions* to tighten said belt around said patient's chest to perform CPR." As can be seen from comparing this language, especially the italicized words, this language differs from the similar (but not identical) verbiage of

Claim 171 by referring to the belt extremities and moving them in directions to perform CPR. Claim 171 merely talks of moving the belt itself in a direction to perform CPR.

However, Figures 7 shows the belt extremities at 206 and 208 moving in the requisite direction. Figure 8 has the extremities 230 and 232 doing the same. Further, the discussion of Figure 1 incorporating a power unit into the device of Figures 1 and 2 starting on page 30 further supports this claim language. There it says:

> It is possible to attach a power unit, such as a prime mover, to the apparatus 10 which could function as an actuator to apply a lateral force to the arm assemblies 16 and 18 to actuate them automatically and in regular, periodic intervals. (Pages 30 and 31.)

As seen in figures 1 and 2, the ends of the belt 40 attach to the struts and move with them. Thus, the specification and the drawings provide clear support for the language of Claim 198's paragraph (D).

Lastly, paragraphs (C) and (D) of Claim 228 state:

> (C) detecting when said belt has placed said patient's chest under compression; and
>
> (D) when said belt has placed shad chest under compression, inducing a defibrillating electric current through said chest.

The specification says of defibrillation:

> The adhesive pad 500 shown in Fig. 16 could contain an electrode which is electrically attached to a voltage generating device as is conventionally known. The adhesive pad 500 could be used in combination with one or more electrodes 504 interposed along the length of the belt 506 or embedded in the backboard 508. These electrodes are used in the conventional manner to induce a current thought the chest 510 which is used for defibrillating the patient's heart. Any combination of two or more electrodes can be used to induce a current to defibrillate the heart.

> The electrodes 504 can be interposed at multiple positions along the length of the belt 506 or in the backboard 508, but there will preferably be a minimum of one electrode on the base 512 (such as the adhesive pad 500 which functions as an electrode) in addition to at least one other electrode 504. The reason it is desirable to have an electrode at least on the base 512 is that at the furthest extent of compression of the chest 510, the distance between the anterior and posterior outer surfaces of the chest 510 will be at a minimum, and the base 512 will be positioned closer to the heart than at any other point in the whole compression/decompression cycle. At this point there is a minimum of resistance to the flow of current which gives the greatest current flow through the heart with the least likelihood of injuring the patient's chest 510 tissue.
>
> The electrodes 504 can be positioned not only circumferentially about the chest 510, but can also be positioned at the same circumferential location but at various longitudinal spacings. (Pages 33 and 34.)

This language along with the above, provides clear support for the independent Claim 228.

As stated above and in general, the independent Claim 128 of the present application concerns a method of CPR treating patients. The method starts with wrapping a belt, with first and second opposite extremities, around and in contact with a substantial majority of a patient's chest near the patient's sternum. The belt is in continuous contact with the patient's chest, including the front, sides, and a portion of the back of the patient's chest with the belt (1) extending around and being in contact with a major portion of the circumference of the chest, and (2) extending around and being in contact with the front, sides and back of the chest, and (3) being substantially inelastic and flexible.

The belt, including any of the extremities of said belt not already fastened around the patient's chest, are fastened to a power unit. An actuator having first and second states is placed in its first state. Lastly, with the actuator in its first state, power from a power

supply is provided to the power unit and the belt moved in a direction to tighten the belt around the patient's chest to perform CPR.

As dependent features, the last two steps are periodically repeated. Further the patient's chest may undergo defibrillation, preferably with the chest under maximal compression typically from the power unit operating on the belt.

As stated in the independent Claim 145, a particular signal is provided to a powered belt tightener coupled to the belt extremities. As dependent features, the belt tightener may include an electric, fluid-pressure, or hydraulic motor. Further, the belt may be tightened substantially equally around the patient's right and left sides.

In the independent Claim 171, power from a power supply to a power unit may be conveyed along a cable to move the belt in a direction to tighten around the patent's chest to perform CPR. The independent Claim 228 includes specifically includes defibrillation. Various of the feature recited above again appear as dependent features. However, as the foregoing discussion shows, all of this finds clear support in the original application as filed.

(vi) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether the examiner erred in objecting to the drawings under 37 C.F.R. § 1.83(a) for not showing the features of the "first and second opposite extremities" of the belt, the "contact with a substantial majority of a patient's chest", the "continuous contact" of the belt with the patient's "front, sides and a portion of the back", the "fastening" of the power unit to the belt, "fastening to an apparatus any of said extremities of said belt not

already fastened to said apparatus," the "powered belt tightener coupled to said belt extremities," the first and second electrodes, and the various types of motors where all of these clearly appear in the figures and were discussed in the five (5) interviews with the examiners which resulted in apparent agreement.

2. Whether the examiner erred in objecting to the specification under 35 U.S.C. § 132(a) because the amendment filed June 26, 2008, added the language referenced in the next sentence to section (A) of the independent claims where the entire application repeatedly shows and discusses the claimed subject matter: The final Office action of April 21, 2009, stated that the allegedly offending language included:

> In particular, wrapping a belt around and "in contact with a substantial majority of a patient's chest near said patient's sternum, said belt being in continuous contact with the patient's chest, including the front, sides and a portion of the back of said patient's chest, said belt (1) extending around and being in contact with a major portion of the circumference of said chest, (2) extending around and being in contact with the front, sides and back of said chest." (Page 3.)

3 Whether the examiner erred in rejecting the Claims 131, 132, 148, 149, 174, 175, 201, 202, 228, and 232 under 35 U.S.C. § 112, first paragraph:

> [A]s failing to comply with the written description requirement. The specification does not disclose a means for detecting when the belt means has placed a patient's chest under compression nor the inducement of a defibrillating electric current to the patient's chest at the time. Additionally, the specification does not disclose a means for detecting when the belt means has placed a patient's chest under maximal compression nor then (sic) inducement of a defibrillating electric current to the patient's chest at that time. (Page 4.)

where the cited items represent standard techniques well known in the art and, as such, were twice brought to the examiner's attention in well known and detailed publications. Further, they do not require any mechanism other than the human operator.

4. Whether the examiner erred in rejecting the Claims 128 to 134, 145 to 156, 171 to 182, 198 to 209, 212, and 229 to 239 under 35 U.S.C. § 112, second paragraph:

> [A]s being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 128, it is not clear what is meant by the phrase, "first and second states."" (sic) In claims 128 and 171, it is not readily apparent how the belt is moved in a direction to tighten the belt around the patient's chest. In claims 145 and 198, it is not readily apparent how the belt extremities are moved in directions to tighten the belt. In claim 228, it is not readily apparent how the belt is moved in a direction to tighten the belt around a patient's chest. The elected species shown in Figure 9 merely suggests a cable (256) connecting a power unit (254) to a belt (258). Claims 128, 145, 171, 198, and 228 each disclose the phrase "to perform CPR." This clause appears to be indefinite since CPR also require (sic) providing air/breath to the patient and that step is not included in the claims. (Pages 4 and 5.)

However, the specification and drawings clearly show how to perform the method of the claims.

5. Whether the examiner erred in rejecting "Claims 128 and 129 . . . under 35 U.S.C. § 102(b) (sic) as being unpatentable over Dedo '579 in view of Cook (3,503,388)" where neither Dedo nor Cook teach or suggest, alone or in combination, any apparatus for or any use of their apparatus for CPR and, in fact, their apparatus cannot find use for CPR.

6. Whether the examiner erred in rejecting "Claims 130-134, 228-239 . . . under 35 U.S.C. § 103(a) as being unpatentable over Dedo in view of Cook '388 and in further view of Barkalow et al. (4,273,114)," for the reasons stated in the immediately prior

paragraph and for the further reasons that Barkalow et al do not and cannot combine with Dedo or Cook and the fact that Barkalow et al is for an entirely different purpose than Dedo or Cook.

7. Whether the examiner erred in rejecting "Claims 145, 146, 152-156, 171, 172, 178-182, 198, 199, 205-209 and 212 . . . .under 35 U.S.C. § 103(a) as being unpatentable over Dedo in view of Cook '388 and in further view of Szpur (5,407,418)," for the reasons given in the second preceding paragraph and the facts that Szpur is for an entirely different purpose than Dedo or Cook, Szpur simply does not combine with Dedo or Cook, and even combining these three references does not reveal or suggest Applicants' invention.

8. Whether the examiner erred in rejecting "Claims 147-151, 173-177 and 200-204 . . . .under 35 U.S.C. § 103(a) as being unpatentable over Dedo in view of Szpur and Cook '388 and in further view of Barkalow et al. (4,273,114)," for the reasons given in the preceding three paragraphs and especially in light of the facts that these four references simply cannot combine and even attempting to combine in the manner suggested by the examiner does not result in or suggest Applicants' claimed method.

(vii) ARGUMENT

(a) Introduction

Unfortunately, the present application has undergone a gruesome ordeal in reaching its present unfortunate posture. Amongst other hurdles, it has suffered through four "final"

Office actions and three personal and two telephonic interviews with the examiners handling it. Agreements reached on the preliminary issue of the *verbiage* of the claims evaporate in the Office action following the adoption of the agreed-upon language with the result that claims were again rejected on this basis.

The claims were rejected for nonenablement because the application does not give explicit instructions for making the standard determinations of when the chest is under pressure or at maximal depression although Applicants cite and include comprehensive, well respected publications (attached below) setting forth these exact features. Further, human observation as well satisfies this language. Nonetheless, the claims are rejected as obvious over patents that simply mention these concepts for CPR with nothing more but are considered enabling nonetheless.

The examiners reject the claims because performing CPR by repeatedly and extremely tightly squeezing a person's chest to compress the heart to stimulate blood flow through the heart presumably provides no aid to respiration. Yet, according to the rejection, the cited references which show an apparatus that allows an emphysemic person to gently squeeze his or her own abdomen as an assist to breathing inherently achieves CPR on a patient *in extremis*.

(b) The History of the Present Application

The present application was filed on August 4, 2003. It constitutes only one in a long series of issued continuations and divisionals starting with (1) U. S. patent application serial number 08/573,465, filed December 15, 1995, and issued as U. S. patent 5,738,637

on April 14, 1998. Then (2) U. S. patent application serial number 09/059,497, filed April 13, 1998, was a continuation of the prior application and issued as U.S. patent 6,234,984 on May 22, 2001. (3) U. S. patent application serial number 09/546,519, filed April 11, 2000, and issued as U.S. patent 6,325,771, on December 4, 2001, was a continuation of the application listed immediately above. (4) Then came U.S. patent application serial number 09/818,102, filed on March 27, 2001, which issued into U. S. patent 6,645,163 on November 11, 2003; it was a divisional of item (2) and a continuation of item (3), above. (5) The present application is a continuation of this last item (4) above. Lastly, to complete the story, U. S. patent 7,186,225 issued on March 6, 2007, from U.S. patent application serial number 10/705,487 which was a division of item (4) above. In other words, from the original application filed in 1995 (item (1), above), five patents have issued, leaving the present application on appeal.

After the filing of the present application with a preliminary amendment on August 4, 2003, Applicant filed a second preliminary amendment on March 21, 2005. This amendment had the purpose of canceling Claims 1 to 40 in the application and adding Claims 41 to 260.

The first Office action issued on May 18, 2005, and constituted a restriction requirement among Claims 1 to 40 which, however, had previously been cancelled. The undersigned attorney telephoned the examiner and explained the situation. Accordingly, a further restriction on the alive claims was issued on January 24, 2006, to which Applicants responded on February 24, 2006.

The first Office action on the merits of the elected claims issued on May 15, 2006. That Office action objected to the drawings and rejected the claims under 35 U.S.C. § 112, first and second paragraphs, rejected some claims under 35 U.S.C. § 102 as anticipated by Mollenauer et al., other claims under 35 U.S.C. § 103(a) as obvious over Mollenauer et al. and the remaining claims under 35 U.S.C. § 103(a) as obvious over Mollenauer et al. in view of Barkalow et al.

In an effort to expedite the examination of the subject application, Applicants' attorney requested and received an appointment for a personal interview scheduled for October 20, 2006. In preparation for this interview, Applicants, on October 18, 2006, submitted their PROPOSED AMENDMENT TO ACTIVE CLAIMS (AS EXAMINED IN THE 05/15/2006 OFFICE ACTION). The scheduled interview, the first interview in the present application, occurred on October 20, 2006, with one of the applicants, Thomas E. Lach, and Applicants' undersigned attorney traveling to the Washington area and meeting with Examiners D. DeMille and T. M. Nguyen.

Applicants then, on November 16, 2006, submitted their Amendment which was written to set forth and accord with the substance and results of the first interview recited above. It did make the claims more specific, and thus narrower. That amendment elicited the *first* final Office action dated April 11, 2007. That Office action removed the rejection under 35 U.S.C. § 112 as to most, but not all of the claims. It also removed the rejection that incorporated Mollenauer et al.

However, the final Office action rejected some claims under 35 U.S.C. § 102 as anticipated by Lach et al. (U.S. patent 4,770,164) and the others under 35 U.S.C. § 103(a)

as obvious over Lach et al. and the remainder as obvious over Lach et al. in view of Barkalow et al. The inventor Ralph Lach of the '164 patent is an inventor in the present application. More importantly, Applicants had cited the Lach et al. patent in their initial submission of August 4, 2003, and had commented upon it as one of the more relevant of the cited references. The examiner, in the May 15, 2006, Office action acknowledged this reference.

In a further effort to expeditiously resolve the issues involved in the present application, Applicants scheduled a second personal interview with the examiner for July 6, 2007. Again, on July 3, 2007, Applicants submitted a PROPOSED AMENDMENT TO ACTIVE CLAIMS (AS EXAMINED IN THE APRIL 11, 2007, OFFICE ACTION). This interview occurred on July 6, 2007 between Applicant Thomas E. Lach, Examiner T. M. Nguyen, and the undersigned attorney.

In light of the results of this interview, Applicants submitted their July 11, 2007 Amendment. That amendment noted that agreement had apparently been achieved as to all issues during the interview. In particular, the amendments to the claims had been worked out in detail during the interview. In fact, the use of the word "torso" to replace "chest" had been specifically suggested by the examiner. Naturally, Applicants acceded to the use of this term in this amendment.

Further, the July 11, 2007 Amendment also argued that the May 15, 2006, Office action did not meet the requirements of having it made "final." Applicants stated that the application of the new reference (Lach et al.) against the claims had not been necessitated by any amendment effectuated by Applicants.

Accordingly, Applicants received the *third* "final" Office action dated August 6, 2007. That paper removed all objections to and rejections of the drawings. It also removed Lach et al. as a reference against the claims.

Most importantly, the August 6, 2007, Office action adopted, as its primary reference against all of the active claims, a drawing by a Roman Szpur that Applicants had attached to their initial submission of the present application on August 4, 2003. This page had appeared as Figure 10 in all of Applicants' patents listed above. All of the patents (except the very earliest) have listed it as "Invention of Another" to unequivocally show that Applicants do not suggest that it was their work. Applicants attached the Szpur drawing to their present application as filed so that the examiners could make use of it as they saw fit.

Thus the August 6, 2007, Office action rejected some claims under 35 U.S.C. § 102 as anticipated by Szpur, others under 35 U.S.C. § 103(a) as obvious over Szpur, still others under 35 U.S.C. § 103(a) as obvious over Szpur in light of Barkalow et al., and others under 35 U.S.C. § 103(a) as obvious over Szpur in light of Szpur's patent 5,407,418, and others as obvious over Szpur in light of Szpur's patent and Barkalow et al.. Interestingly, this Office action contained no objection to or rejection of the claims under 35 U.S.C. § 112.

To prepare a response to the August 6, 2007, Office action, Applicants' attorney engaged in the two telephonic interviews of October 2 and 11, 2007 (bringing the number of interviews concerning this application to four). In fact, Applicants did, on October 15, 2007, file a response to the August 6, 2007, Office action.

Subsequently, on November 8, 2007, the Patent and Trademark Office issued the *fourth* final Office action in the present application. This Office action raised objections to the drawings and specification and rejections of the claims based on 13 issues not brought to the surface in the preceding Office action of August 6, 2007. These new rejections, *inter alia*, complained of the language *suggested by the examiner* at the July 6, 2007, personal interview and cited two references not previously applied to the claims. One of the references (Szpur U.S. patent 5,407,418) had been previously listed by Applicants and the other (Dedo U.S. patent 4,004,579) was identical to a reference (Nasa Tech Briefs—MSC—22148-1—April 1995, Volume 19, Issue 04, Page 82) also disclosed by Applicants[1].

The Office action of November 8, 2007, in the section entitled "Conclusion," stated, "Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a)." (Emphasis in original.) Of course, Applicants' October 15, 2007, Response had effectuated *no amendment* to the application. It had only argued the inapplicability of the Szpur drawing as a reference.

The perilous posture of the subject application elicited a telephone call from the undersigned attorney to the Director of Group 3700. As a result of that call, the final Office action of November 8, 2007, was withdrawn and the Office action of January 28, 2008, issued. This latter paper did *not* constitute a final Office action.

[1] In fact, the NASA Tech Brief had been cited against the claims and overcome in the prosecution of the earlier filings listed above in Section VII (b), above.

The new January 28, 2008, Office action contained objections and rejections not included in the prior, withdrawn Office action and even one never previously seen in the history of the application. Thus, the oath and the drawings, *as originally filed*, were now objected to for the first time.

In yet another effort to resolve the issues involved in the present application, Applicants' undersigned attorney scheduled a fifth (third personal) interview with the examiners handling it. Prior to the interview, Applicants, on April 8, 2008, submitted their CLAIMS AND REFERENCES UNDER DISCUSSION FOR INTERVIEW OF APRIL 10, 2008.

In fact, the interview took place on the indicated date. Applicant Thomas Lach and the undersigned attorney attended the interview with the examiners in Alexandria, Virginia. Unfortunately, no issue reached resolution. In fact, the examiners stated that the prior suggestion (of the *examiner* in the second personal interview of July 6, 20) of the word "torso" instead of "chest" no longer seemed appropriate.

Consequently, the examiners filed a brief INTERVIEW SUMMARY, and Applicants filed their AMENDMENT of June 25, 2008, which included a new declaration from all of the inventors and attached the publications STANDARDS FOR CARDIOPULMONARY RESUSCITATION (CPR) AND EMERGENCY CARDIAC CARE (ECC) in the supplement to the Journal of the American Medical Association, dated February 18, 1974, Vol.. 227, page 833[2] and TRANSTHORACIC RESISTANCE IN

[2] Applicants had also attached a copy of these articles with their prior April 8, 2008, submission, CLAIMS AND REFERENCES UNDER DISCUSSION FOR INTERVIEW OF April 10, 2008.

HUMAN DEFIBRILLAITON, by R.E.. Kerber et al., *Circulation*, Vol. 63, No. 3, March 1981. The latter had the purpose of showing, *inter alia*, that determining chest compression during CPR and applying a defibrillating current *at that time*, especially at maximal compression, constituted a known standard.

On April 21, 2009, the *fifth* final Office action in the present application issued. (The fourth final Office action had been withdrawn as indicated above.) The present appeal followed.

(c) The Objection to the Drawings under 37 C.F.R. § 1.83(a)

The final objection to the drawings under 37 C.F.R. § 1.83(a) in the April 21, 2009, final Office action states:

> 1. The drawings are objected to under 37 C.F.R. 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "first and second opposite extremities" of the belt, the "contact with a substantial majority of a patient's chest", the "continuous contact" of the belt with the patient's "front, sides and a portion of the back", the "fastening" of the power unit to the belt, "fastening to an apparatus any of said extremities of said belt not already fastened to said apparatus", the "powered belt tightener coupled to said belt extremities', the first and second electrodes and the various types of motors must be shown or the feature(s) canceled from the claim(s). (Page 2.)
>
> * * * * *
>
> As to the drawings, applicant argues that the claims under examination were generic to Figures 7-9; thus species selection requirement was artificial and the various elements shown in Figs. 7-9 can be drawn together to satisfy the requirements of 37 CFR § 1.83(a). This is erroneous unless the specification clearly provides a clause that states that elements from one species can be incorporated by another

> species. Since the specification does not disclose such a clause, the applicant is precluded from taking elements from one or more species and combining them with another species in an attempt to satisfy the requirements of 37 CFR § 1.82(a) (sic) for a particular species. (Page 12.)

The objection set forth in the quoted paragraphs suffers from two infirmities. First, the application itself states:

> In describing the preferred embodiment of the invention which is illustrated in the drawings, specific terminology will be resorted to for the sake of clarity. However, it is not intended that the invention be limited to the specific terms so selected and it is to be understood that each specific term includes all technical equivalents which operate in a similar manner to accomplish a similar purpose. (Page 10.)
>
> * * * * *
>
> A converter for converting the above described applied force into the resultants includes all equivalents to the preferred force converter. A converter need not merely redirect a specific force but could amplify, reduce or signal a device to generate other forces, by the application of a force. (Page 24.)
>
> * * * * *
>
> The preferred embodiment of the present invention is one device the Applicants have found advantageous for converting the downward force 112 into the three resultant forces 120, 122, and 124. The Applicants know that many apparatuses are equivalent to, and could be substituted for the preferred apparatus to provide the force conversion described in association with Fig. 3. Although it is impossible to list every mechanical device which one skilled in the art will know can convert an applied force into the desired resultant force, some of the many equivalents are described herein. However, this is not an exhaustive list, and other equivalents exist as will become apparent to those skilled in the art. (Pages 25 and 26.)
>
> * * * * *

FIG. 6 illustrates a diagrammatic illustration of another equivalent to the preferred embodiment . . . . (Page 27.)

* * * * *

Many illustrations show equivalent substitute devices for converting an applied force into the desired resultant forces. Most of those described above show purely mechanical equivalents to the preferred embodiment. As a person skilled in the mechanical arts will quickly find, there are many other different substitutes for the preferred embodiment. These devices are equivalent to the preferred embodiment or one of the alternatives described above and shown in the drawings. In addition to purely mechanical alternatives to the preferred embodiment, it is of course possible to combine mechanical, electrical, hydraulic and many other elements to arrive at an equivalent substitute for the preferred embodiment. These combination equivalents are discussed below. (Page 29.)

In Fig. 7 a mechanical and electrical combination equivalent is shown . . . . (Page 29.)

Fig. 8 *shows still another equivalent to the present invention* in a diagrammatic illustration including a hydraulic cylinder 220, fluid lines 222 and 224, and pistons 226 and 228. The belt ends 230 and 232 are mounted to the pistons 226 and 228. Upon actuation of an actuator 234, hydraulic fluid is forced into the hydraulic cylinder 220 forcing the pistons 226 and 228 toward one another longitudinally, thereby exerting a force on the belt ends 230 and 232. The actuation of the actuator is accomplished by a downwardly force which exerts a similar force to a patient's chest lying directly beneath the hydraulic cylinder 220. (Page 30, emphasis added.)

The actuator 234 could be attached to a central piston which compresses a fluid within a hydraulic cylinder. Upon actuation of actuator 234, the hydraulic fluid within the cylinder is compressed and is conveyed through the lines 222 and 224 and the pistons 226 and 228 are driven inwardly as described. This embodiment is also equivalent to the preferred embodiment. (Page 30.)

It is possible to attach a power unit, such as a prime mover, to the apparatus 10 . . . . As shown in Fig. 9, the power unit 254 . . . . (Pages 30 and 31.)

* * * * *

> While certain preferred embodiments of the present invention have been disclosed in detail, it is to be understood that various modifications may be adopted without departing from the spirit of the invention or scope of the following claims. (Pages 34 and 35.)

As seen from these quotations, Applicants have created a system for applying CPR (Cardio-Pulmonary Resuscitation) that involves applying a downward force that converts into two resultant forces, the first still a downward force and the second a circumferential force as shown in Figure 3. As described in the application, this type of CPR achieves superior results than either of these forces acting alone. This desired objective can be achieved by all sorts of equipment with components that are the equivalent and substitutable with others as the above quotations clearly state. The above quotations can have no other purpose. For this reason alone, the final objection to the drawings under 37 C.F.R. § 1.83(a) cannot stand.

The final objection to the drawings, quoted above, suffers from a further infirmity. The claims under appeal cover a *method* and variations. A requirement for the selection of species based on apparatus claims obviously does not accord with the reality of the method under review. Thus, different drawings may and do show alternative mechanisms all directed to the *same claimed method.* And they depict the method in different stages acting through different mechanism components. Thus, for example, Figure 7 shows the switch 212. Clearly, the hydraulic-pneumatic mechanism of Figure 8 will also utilize a switch (to turn on and off the pressure to the cylinder 220) to apply and release pressure in response to the actuator 234. While this would seem clear for mechanical claims, a discussion of the method cannot be separated between these two figures. They both accomplish the same

method. Forcing an election between these two mechanical drawings for, in reality, the *same* method displayed can only be considered artificial and unsupportable. For this reason as well, the final objection to the drawings should be reversed. This action is sincerely requested.

Further, the features of the claimed invention do, in fact, appear in the drawings. Thus, the "first and second opposite extremities" of the belt appear in Figures 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 12, 13, 15, and 16. The "contact with a substantial majority of a patient's chest" appears in Figures 1, 2, 9, 13, 15 and 16. The "continuous contact" of the belt with the patient's "front, sides and a portion of the back" appears in Figures 1, 2, 9, 13, 15, and 16. The method steps of "fastening" of the power unit to the belt and the "fastening to an apparatus any of said extremities of said belt not already fastened to said apparatus," because they have already been accomplished, appear in all of the figures and receives discussion, *inter alia*, on pages 19 to 21 and on pages 28 and 29 of the application. Obviously, anyone with even minimal skills in the art would know that the belt ends have to be attached to whatever apparatus is employed. The "powered belt tightener coupled to said belt extremities' appears in Figures 8 to 10. The first and second electrodes appear in Figure 16 and receive discussion on pages 33 and 34. The "various types of motors" appear in Figures 7 to 10 and receive discussion on pages 29 to 31 of the application. Applicants have complied with the statutory requirements for their disclosure. Accordingly, the final objection to the drawings on this basis should be reversed.

(d) The Objection to the Specification under 35 U.S.C. § 132(a)

The objection to the specification under 35 U.S.C. § 132(a) in the April 21, 2009, final Office action states:

> 2. The amendment filed June 26, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: substantially subsection (A) of each of the independent claims. In particular, wrapping a belt around and "in contact with a substantial majority of a patient's chest near said patient's sternum, said belt being in continuous contact with the patient's chest, including the front, sides and a portion of the back of said patient's chest, said belt (1) extending around and being in contact with a major portion of the circumference of said chest, (2) extending around and being in contact with the front, sides and back of said chest." (Page 3.)
>
> * * * * *
>
> As to the specification, applicant appears to be arguing that the July 11, 2007, amendment did not introduce new matter when in fact it did. During the interview with Mr. Lach and the undersigned attorney (sic) on July 6, 2007, examiner attempted to work with the Mr. Lach and his attorney to obviate the Lach et al. '164 reference such that applicant's invention could be allowed. Unfortunately, claim language was agreed to that would obviate the Lach reference but it was not discovered until later that said claim language was not supported by the specification and thus must be considered new matter. Once this discovery was made, the applicant was notified and provided with a non-final rejection so that applicant could properly respond to the new matter rejection. The applicant also argues that the last office action dated January 2, 2008 made clear that the ultimate objective of the office action was to refuse to allow the issuance of the present application. This is definitely not the case. *In Paragraph 4 of the last Office Action dated January 2, 2008, the examiner merely laid out his plan for rejecting the claims when the new matter was removed to expedite the prosecution.* It was the examiner's hope that by revealing the office's most likely course of action, the applicant would proceed in another direction to try to

> overcome the Lach reference or distinguish his invention from the prior art. Applicant also argues that the claim language, particularly the clauses of Subsection (A) of the independent claims is based on the actual disclosure but there is no support in the specification that the belt is wrapped around "in **continuous** contact with the patient's chest, including front, sides and a portion of the back of said patient's chest." In particular, applicant argues that the clause is supported by the figures, but Figure 9 of the elected Species does not support the clause. (Pages 12 and 13, italics added, bold face in original.)

Initially, as indicated in the prior section, the phrase from the rejection, "Once this discovery was made, the applicant was notified and provided with a non-final rejection" shows the difficulty of attempting to achieve a resolution of the outstanding issues affecting the present application. Initially, the final Office action (the third) of November 8, 2007, was issued. The "discovery was made" by the undersigned attorney telephoning the Director of Group 3700 and complaining about the unfortunate treatment he had received in attempting to represent his client regarding the present application. Only then was a nonfinal Office action (of January 28, 2008) issued. And, it contained numerous rejections never before seen in the present application.

Proceeding to the merits of the objection, the present application says of the belt:

> The belt 40, which extends around the front, sides and back of the chest, is substantially inelastic and flexible. A plurality of indicia 50 is printed on the exposed surface of the belt 50. The belt 40 attaches to the strut 34 on one side of the chest 12, and extends around a major portion of the circumference of the chest to attach to the other strut 36. When the assemblies 16 and 18 pivot around the pivot pin 20, the belt 40 is tightened by the struts 34 and 36 to which the belt 40 attaches.
>
> Although the belt 40 is described as extending around the front, sides, and back of the chest, the belt may be made up of two or more component parts, such as a pair of belts.

> This pair of belts could extend from attachment to the struts 34 and 36, extending downwardly past the sides of the patient's chest to rigid attachment to a board which spans the width of the back of the chest. Therefore, "a belt wrapped around the chest" can be made up of two or more belt components which extend around portions of the chest circumference in combination with other rigid or flexible components. Pages 16 and 17.)
>
> * * * * *
>
> The belt 40 extends through slots 44 formed in a backboard 42 which, *when in use*, is positioned beneath the chest 12 of the patient. The belt 40 *preferably* seats against a sliding mechanism 43 which permits sliding of the belt 40 along the length of the chest 12 for positioning of the belt 40 on the chest. (Page 18, emphases added.)

Clearly, the specification, as originally filed, contained language that supports the present claims.

Further, the drawings, as originally filed, also provide clear support for the claims. The law is clear to the effect that the *drawings* themselves constitute part of the "written description" of a patent, a patent application, and a provisional application, *Vas-Cath Incorporated, supra; Cooper Cameron Corp. v. Kvaener Oilfield Products, Inc.*, 291 F.3d 1317 (Fed.Cir. 2002), citing *Vas-Cath.* Thus, the drawings show all of the referenced features, as thoroughly discussed in the immediately prior section.

(e) The Rejection of Claims under 35 U.S.C. § 112, First Paragraph

The final rejection of the claims under 35 U.S.C. § 112, first paragraph states:

> 4. Claims 131, 132, 148, 149, 174, 175, 201, 202, 228, and 232 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The specification does not disclose a means for detecting when the belt means has placed a patient's chest under compression nor the inducement of a defibrillating current to

> the patient's chest at the time. Additionally, the specification does not disclose a means for detecting when the belt means has placed a patient's chest under maximal compression nor then inducement of defibrillating electric current to the patient's chest at that time. (Page 4.)
>
> * * * * *
>
> As to the claim rejections under 35 U.S.C. § 112, applicant argues that since defibrillation constitute (sic) standard techniques in the art of resuscitating patients suffering from cardiac arrest, the particulars of defibrillation as part of the applicant's invention is not necessary. Examiner respectfully disagrees with this argument. Indeed the prior art may disclose the combination of defibrillation and CPR, but applicant specifically claims a method wherein defibrillation occurs at maximal compression thus, (sic) applicants particular process or step of determining maximal compression should be adequately disclosed. (Pages 13 and 14.)

Defibrillation constitutes a technique very well and long known in the art. The reference, Barkalow et al., *cited by the examiner in the rejections* under 35 U.S.C. § 103(a) on August 6, 2007, and January 28, 2008, provides diagrams for CPR and also for CPR under maximal chest pressure in Figures 6 to 8. Its discussion (starting at col. 5, line 33) says:

> Referring now also to FIGS. 2, 3, 4 and 5, details of the cardiac compressor pad 19 of the present invention are illustrated. The compressor pad 19 is connected to and is actuated by the CPR unit 10 for compressing the patient's sternum and thus compressing the patient's heart between the sternum and spine. The compressor pad 19 as best illustrated in FIG. 6 is positioned anterior to the to the patient's heart 45 in contact with the lower portion of the patient's sternum 46. The body 50 of the compressor pad 19 is preferably molded from an elastomer of a semi-rigid type. . . .
>
> The anterior electrode 48 covers a relatively large area of the face 49 and is preferably five square inches or more in area. Electrode 48 is isolated electrically from all metal parts of the CPR assembly except that is electrically

connected to a terminal 54 disposed at the top of the assembly by multiple internal flexible leads shown in phantom at 55 in FIG. 2. . . . (Col. 5, lines 33 to 61, boldface deleted.)

* * * * *

Referring to FIGS. 1 and 6 it is illustrated that the base 12 of the compressor is provided with a posterior electrode 75. The posterior electrode is disposed on the face of the base 12 for compression between the base 12 and the bare back of the patient to create good ohmic contact therebetween. Like the anterior electrode 48, the posterior electrode may be fabricated from a silver or gold plated mesh screen or may be integrally formed in the base 12. In any event, the posterior electrode must be electrically insulated from the rest of the CPR unit. Although not illustrated herein, the base 12 may be contoured to more closely conform to the patient's back and the electrode may be disposed on an elastomer pad which is secured to the base 12 to insure that the electrode closely conforms to the patient's back and a good ohmic contact is created therebetween. . . . (Col. 6, lines 23 to 39, boldface deleted.)

* * * * *

Although use of a posterior electrode disposed on the base of the compressor requires the application of more electrical power to the defibrillating electrodes the amount of power required is still substantially lower than that required when using conventional chest mounted electrodes, because of the proximity of the anterior and posterior electrodes to the heart *during the systolic portion of the compressor cycle.* (Col. 6, lines 57 to 65, emphasis added.)

* * * * *

The invention further includes means for synchronizing the defibrillator and the compressor, preferably comprising a pressure sensitive switch 105 for sensing pneumatic pressure within the power cylinder 17 of the CPR unit 10. *The pressure switch 105 acts to disable the defibrillator unit except when pressure within power cylinder 17 reaches a predetermined value. This ensures that when (sic) the defibrillator counter shock is only applied to the patient's heart during compression of the patient's heart, or during a systolic portion of the compressor cycle. Preferably the pressure switch set to allow the application of a*

defibrillating shock only during, or close to, the period of maximum compression in the compressor cycle. . . . Adjustability of the pressure switch is also important where it is desirable to only apply the defibrillating shock at the point of maximum compression since the maximum compression pressure will vary with different patients.

It is to be understood that standard defibrillator and monitor circuits may be employed with the present invention although, because of the certain unique advantages presented by the present invention, a defibrillator of less power than standard defibrillator circuits may be employed. . . . These standard, commercially available, defibrillating circuits could be modified for use with the present invention by wiring these standard paddle switches or their equivalents in series with pressure actuated switch 105 such that manual actuation of the defibrillator is effective only during the time period when the pressure in power cylinder 17 closes switch 105, indicating that the compressor is in a systolic portion of the compressor cycle. (Col 7, lines 5 to 41, emphasis added, boldface deleted.)

* * * * *

When a gross arrhythmia, such as ventricular fibrillation is detected and it is desirable to apply a defibrillation shock to the heart, the combination of the anterior electrode 48 and the posterior electrode 75 provides a short, direct electrical path through the hear, substantially reducing the amount of power required to defibrillate the heart. Referring now also to FIGS. 7 and 8, it is illustrated that this electrical path is further shortened by the action of cardiac compression. Referring now specifically to FIG. 7, the compressor pad 19 is illustrated in the diastole position or fully retracted position and the uncompressed heart is illustrated at 45. With reference now to FIG. 8 it is illustrated that by synchronizing defibrillation shock with the systole portion of the compression cycle, the action of the compression cycle, the action of the compressor substantially shortens the electrical path through the heart, compressing the heart between the sternum 46 and the backbone 112, between anterior electrode 48 and posterior electrode 75. Synchronizing the application of defibrillating shock with the systole portion of the compression cycle also compresses the anterior and posterior electrodes 48 and 75 against the chest and back, respectively, of the patient to create good ohmic

> contact therebetween.. Thus, in addition to providing a good monitoring path for the electrical activity of the heart during CPR., the present invention provides an improved electrical path for administration of electrical defibrillation to the patient by allowing effective defibrillation at reduced levels of total current and thus total electrical energy applied to the patient's body and heart. (Col. 8, lines 13 to 45, boldface deleted.)
>
> * * * * *
>
> [I]f, while monitoring the electrical activity of the patient's heart, a gross arrhythmia, such as ventricular fibrillation is detected, the operator may apply definitive therapy such as defibrillation shock to the patient's heart by simply actuating a manual push button on the defibrillator, the manual push button corresponding to the paddle buttons normally provided on conventional defibrillator paddles. These paddle buttons would simple be depressed until the series wired synchronizing pressure switch 105 closes, determining that s systolic portion of the compression cycle has been reached and triggering the defibrillation shock. (Col. 8, lines 47 to 59.)
>
> * * * * *
>
> The switch 105 will generally be adjustable such that the operator may precisely time the defibrillation shocks *to the point of maximum compression of the CPR unit.* (Col. 9, lines 1 to 4., boldface deleted., emphasis added.)

(Boldfacing of "FIGS." and the numerals deleted, emphases added.) It, in fact, supplies no greater and no less information than the discussion on pages 33 to 34 of the present application. It refers to procedures well developed in 1979, the date of the filing of the Barkalow et al. application. The reason for this is clear: the disclosure need not provide an encyclopedia of all that is known and relevant in the art. It need only enable one skilled in the art to make and use the invention.

The *JAMA* and *Circulation* references previously cited to the Examiner in Applicants' CLAIMS AND REFERENCES UNDER DISCUSSION FOR INTERVIEW

OF APRIL 10, 2008, submitted on April 8, 2008, and their AMENDMENT of June 26, 2008, and currently attached as Appendix (ix) EVIDENCE APPENDIX here, clearly provide standard, long known, and unquestioned information as to the defibrillation technique. The latter reference, *Circulation.* 1981; 63; 676-682, says:

> The effects of paddle contact pressure were studied in closed-chest dogs anaesthetized with chloralose-urethane and ventilated mechanically. Contact pressure was assessed in four dogs by designing a paddle-holding apparatus that enabled the operator to adjust the tension of a spring scale connecting the paddle levers and thereby to select paddle contact pressure against the thorax. We estimated light contact pressure with hand-held paddles to be the equivalent of 10 N of tension in the paddle-holding apparatus. Firm pressure was estimated to be equivalent to 50 N of tension, equivalent to a fivefold increase in effective contact pressure. Values of peak current obtained at these tensions were similar to currents obtained in preliminary animal studies that used lightly and firmly applied hand-held paddles. . . .
>
> We reasoned that TTR [transthoracic resistance] might be related to the physical separation between the paddles, and that this would in turn be related to chest width (i.e., lateral chest diameter), as anterolateral paddle placement was used, and possibly also to the thickness of the chest wall tissues. . . . (Page 677.)
>
> * * * * *
>
> **Effect of Paddle Contact Pressure on TTR**
>
> Shocks using light and firm paddle pressures (in random order) were delivered to nonfibrillating dogs using 8.5-cm paddles coated with Redux paste and a 40-J energy dose (2 J/kg body weight). Light paddle contact pressure resulted in a TTR of 48 ± 22 Ω whereas with firm contact pressure TTR was 25 % lower, 36 ± 17 Ω ($p < 0.01$) (fig. 5). Peak current flow was 21 ± 8 A with low contact pressure and 23 ± 6 A with firm pressure ($p < 0.01$), a 10% increase (fig. 5). Using large (13 cm) paddles and a lower energy dose (20 J), low contact pressure resulted in a TTR of 42 ± 4 Ω and a peak current flow of 15 ± 1 A. Firm contact pressure resulted in a TTR of 29 ± 1 Ω ($p < 0.01$), a 31 % lower value, and a peak current flow of 18 ± 0 A ($p < 0.01$), a 16%

increase. Similar decreases in TTR and increases in peak current occurred with firm pressure even when bare paddles were applied to the shaved skin. With 8.5 cm paddles and a 40-J energy dose, TTR decreased from 95 ± 15 to 60 ± 6 Ω ($p < 0.05$) as contact pressure was increased from light to firm. Peak current flow increased from 14 ± 1 to 18 ± 1 A ($p < 0.05$).

Discussion

The main findings of this investigation are (1) the range of TTR in humans is very wide; (2) TTR is weakly related to body weight and more strongly to chest width; . . . (4) TTR is lowered and current increased by applying paddles firmly to the chest . . . . (Page 679.)

Our data show that TTR is weakly related to body weight. However, TTR is more clearly related to chest width, a relationship also noted by Ewy et al., who studied patients undergoing elective cardioversion with anteroposterior paddles and found a similar relationship ($r = 0.82$) between TTR and anteroposterior chest diameter. If the energy selected is low and therefore marginal for defibrillation, a high TRR might result in inadequate current flow and failure to defibrillate a heavy, big-chested subject. . . . (Page 680, footnotes deleted.)

Because TTR can be decreased by use of large paddles and firm contact pressure, such maneuvers might be of critical importance in a very large patient with high TTR. (Page 680.)

* * * * *

Although firm paddle contact pressure is advised in defibrillation, an experimental basis for this recommendation has been lacking. This study shows that firm pressure is indeed beneficial because it reduces TTR and increases current flow. It appears that a substantial proportion of TTR is at the paddle skin interface. Firm mechanical contact pressure probably reduces TTR by increasing the number of low-resistance electrical contact points between the paddle surface and the skin. A more uniform dispersion of the electrode paste may also occur with higher contact pressure, but firm contact pressure reduced TTR even when bare paddles were used.

> Factors of paddle size and paddle contact pressure appear to be additive in reducing TTR. In the same dogs, standard-size paddles applied with light contact pressure yielded a mean TTR of 48 Ω, whereas large paddles applied firmly reduced TTR to 29 Ω. Thus, increasing both paddle size and contact pressure resulted in a combined TTR decline of 40%. (Page 681, footnotes omitted.)
>
> * * * * *
>
> We conclude that in human defibrillation TTR varies widely and is best related to chest size.. TTR can be substantially reduced and peak current flow increased during defibrillation by using large paddles and firm paddle contact pressure. These maneuvers will maximize current flow from presently available defibrillators. (Page 681.)

The former reference alluded to above, The Journal of the American Medical Association ("JAMA"), February 18, 1974, Vol. 227, No 7, *Standards for CPR and ECC*, said in 1974:

> **Defibrillation**
>
> * * * * *
>
> In instances of apparent cardiac arrest secondary to hypoxemia, e.g., drug overdoses, CPR for a period of two minutes is recommended with reevaluation prior to the delivery of an unmonitored defibrillator shock.
>
> The optimum amount of electrical energy has not been established and (sic) there are no conclusive data concerning the ideal defibrillator output waveform. The output delivered into a 50-ohm load should range from 0 to at least 250 watt-seconds, preferably 300 watt-seconds for the conventional Lown waveform.. This range will provide adequate energy for the majority of patients. The energy requirements of defibrillators with other waveforms may vary from this range. In emergency situations, it has been customary to deliver a maximum shock of 400 joules (watt-seconds) for cases of ventricular fibrillation. However, lower settings frequently are effective in converting ventricular fibrillation and ventricular tachycardia and produce less myocardial damage. The damage resulting from defibrillator shocks is directly proportional to the energy used, and maximal settings, when not required, may further impair an

> already damaged myocardium. (Pages 856 to 857, footnotes deleted.)

These references, in the reverse order, make the following clear:

First, excessive electrical shock in defibrillation may well damage the heart. (The *JAMA* article.) Second, greater paddle (i.e., electrode) pressure and a smaller anteroposterior distance reduces the amount of electricity required for defibrillation. (The *Circulation* article.) These objectives are clearly met by defibrillating during CPR depression, preferably maximal CPR depression. (The Barkalow et al. patent.) All of this was well established prior to the filing (on December 15, 1995) of the first and earliest of the patent applications (serial number 08/573,465) whose filing date the present application claims the benefit.

Stated in other words, these three published references show that applying pressure reduces impedance between the paddles and thus the amount of current to effect defibrillation. In particular, a smaller gap between the paddles increases the effectiveness of defibrillation. Further, greater pressure on the paddles helps reduce the gap in transthoracic (i.e., anteroposterior) defibrillation. Further, the net result is less damage, possibly mortal, to the patient. Thus, the present application under appeal has clearly enabled the present claims where it says:

> The adhesive pad 500 shown in Fig. 16 could contain an electrode which is electrically attached to a voltage generating device as is conventionally known. The adhesive pad 500 could be used in combination with one or more electrodes 504 interposed along the length of the belt 506 or embedded in the backboard 508. These electrodes are used in the conventional manner to induce a current through the chest 510 which is used for defibrillating the patient's heart.

> Any combination of two or more electrodes can be used to induce a current to defibrillate the heart.
>
> The electrodes 504 can be interposed at multiple positions along the length of the belt 506 or in the backboard 508, but there will preferably be a minimum of one electrode on the base 512 (such as the adhesive pad 500 which functions as an electrode) in addition to at least one other electrode 504. The reason it is desirable to have an electrode at least on the base 512 is that at the furthest extent of compression of the chest 510, the distance between the anterior and posterior outer surfaces of the chest will be at a minimum, and the base 512 will be positioned closer to the heart than at any other point in the whole compression/decompression cycle. At this point there is a minimum of resistance to the flow of current which gives the greatest current flow through the heart with the least likelihood of injuring the patient's chest 510 tissue.

(Page 33, line 4, to page 34, line 4.) All of the above clearly appears in the references as discussed above. Applicants not need to repeat all of the minor, standard, conventional details here. Further, the steps of "detecting when said belt has placed said patient's chest under compression; and, when said belt has placed said chest under compression, inducing a defibrillating electric current through said chest" need not be done *automatically*. Human visualization and application suffice. Indisputably, these actions were well known to the ordinarily skilled artisan well before the filing of the original application that has led to the present application.

As indicated at the very beginning of this section, the Examiner based this final rejection on 35 U.S.C. § 112, first paragraph. Under this statutory standard, the application need only "enable any person skilled in the art to make and use the invention." This hypothetical, skilled artisan, clearly has a greater level of skill than one "*ordinarily* skilled in the art" of 35 U.S.C. § 103 for obviousness. Appellants-Applicants have accomplished

the statutory requirement of enabling those *skilled in the art* to make and use their invention. No more is required. Accordingly, the rejection on this basis should be reversed.

(f) The Rejection of Claims under 35 U.S.C. § 112, Second Paragraph

The final rejection of the claims under 35 U.S.C. § 112, second paragraph, stated as follows:

> 5. Claims 128-134, 145-156, 171-182, 198-209, 212, and 228-239 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 128, it is not clear what is meant by the phrase, "first and second states." In claims 128 and 171, it is not readily apparent how the belt is moved in a direction to tighten the belt around the patient's chest. In claims 145 and 198, it is not readily apparent how the belt extremities are moved in directions to tighten the belt. In claim 228, it is not readily apparent how the belt is moved in a direction to tighten the belt around a patient's chest. The elected species shown in Figure 9 merely suggests a cable (256) connecting a power unit (254) to a belt (258). Claims 128, 145, 171, 198 and 228 each disclose the phrase "to perform CPR". This clause appears to be indefinite since CPR also require (sic) providing air/breath to the patient and that step is not included in the claims. (Page 4.)
>
> * * * * *
>
> Applicant also argues that the two states of "on" and "off" or "forward" and "reverse" are not indefinite; however, there is no language in the specification to infer that the two states refer to "on" and "off" or "forward" and "reverse". That is, there is no language to preclude a person from concluding that the "two" states can be "fast" and "slow"; thus the phrase "first and second states" is indefinite. Finally, applicant argues that moving the belt in a direction to tighten the belt around a patient's chest is clear, yet (sic) Fig. 9 does not enhance the understanding of how this is done but rather provides a confusing picture of how the belt can be possibly tightened. In particular, it would appear to be impossible for

> the cable (256) as shown in Fig. 9 as being perpendicularly attached to the belt as being able to tighten up the belt by actuating the cable. (Page 14.)

The specification gives clear directions as to the two states. They can be electrical as in Figures 1, 7, 9, and 10 or pneumatic as in Figures 8, 9 and 10. However, the specification states:

> In Fig. 7, a mechanical and electrical combination equivalent is shown diagrammatically including an actuator 200 and electric motor 202 attached to a base. The motor 202 has a pair of belt ends 206 and 208 attached to a driveshaft 210. Upon depression of the actuator 200, a pressure-sensitive switch 212 actuates the motor 202, rotating the driveshaft 210 and exerting a linear force on the belt ends 206 and 208 (Pages 29 and 30.)
>
> Fig. 8 shows still another equivalent to the present invention in a diagrammatic illustration including a hydraulic cylinder 222, fluid lines 222 and 224, and pistons 226 and 228 slidingly mounted within the cylinder 220. The belt ends 230 and 232 are mounted to the pistons 226 and 228. Upon actuation of an actuator 234, hydraulic fluid is forced into the hydraulic cylinder 220 forcing the pistons 226 and 228 toward one another longitudinally, thereby exerting a force on the belt ends 230 and 232. . . .
>
> The actuator 234 could be attached to a central piston which compresses a fluid within a hydraulic cylinder. Upon actuation of actuator 234, he hydraulic fluid within the cylinder is compressed and is conveyed though the lines 222 and 224 and the pistons 226 and 228 are driven inwardly as described above. This embodiment is also equivalent to the preferred embodiment.
>
> It is possible to attach a power unit, such as a prime mover, to the apparatus 10 [of Figures 1 and 2] which could operate as an actuator to apply a lateral force to the arm assemblies 16 and 18 to actuate them automatically and in regular, periodic intervals. As shown in Figure 9, the power unit 254 has a cable 256 which attaches to a belt 258. The device providing a mechanical force to the belt 258 may be located in the power unit 254 and the cable 256 is then rotatingly driven or longitudinally, reciprocatingly driven to

> tighten and loosen the belt 258. Alternatively, the actuator which tightens and loosens the belt 258 could be located beneath the belt and the cable 256 would merely convey electrical power or fluid pressure to the actuator. The power unit 254 may use computer controls to time the application of force. (Pages 30 and 31.)

This material provides clear direction of how to make and use the invention. As for the perceived problems with Figure 9, the power unit 254 could rotate the cable 256 or drive it longitudinally and reciprocatingly to tighten and loosen the belt 258. Alternately, a small motor (actuator) could be located under the belt 258 and receive electrical or pneumatic power to effect the tightening and loosening. No doubt can exist as to what this figure, let alone the others discussed in the quotation, is teaching.

Thus, one skilled in the appropriate art recognizes the phrase "first and second states" as meaning, first, "on and off. " Alternately, the states may also simply differentiate in terms of current or applied voltage as is standard in the relevant art of electromechanical devices. As for the pneumatic or hydraulic version of Figure 8, the power unit, in the first state, may have closed valves and in the second state, open valves. Thus, with various types of power units shown in the figures and discussed in the specification, the terms "first and second states" depends upon the actual type of power unit employed. However, one skilled in the art, with the types of apparatus shown in the figures and discussed in the specification, would clearly know the meaning of these terms. In one state, the power unit tightens the belt. In the other, it allows the belt to loosen. One skilled in the art could not have any doubt about this.

The final Office action also says, "It is not readily apparent how the belt is moved in a direction to tighten the belt around the patient's chest," "how the belt extremities are

moved in directions to tighten the belt," and "how the belt is moved in a direction to tighten the belt around a patient's chest. A careful reading of the entire application shows exactly how this is accomplished and what is happening. The belt ends are pulled by whatever means in the directions that they point to. In this way, and only in this way, could they tighten the belt around the patient's chest. No doubt can exist on this score for either the manual or the powered devices. Rejecting the application on this basis cannot withstand scrutiny.

Lastly the portion of the rejection which states that the method requires "providing air/breath to the patient and that step is not included in the claims" simply has blinded itself to the operation of the present invention (and the discussion in the references of the *Journal of the American Medical Association* and *Circulation* also attached here). First, the final Office action has provided no reference of basis for this assertion. For this reason alone, it cannot stand.

Further, as shown in Applicants' cited literature references and in the Barkalow et al. reference *cited by the examiners in the final Office action*, supplying air may or may not be required. It may be, *but only if the patient has stopped breathing*. Further, the method recited in the present claims would clearly, but inherently, provide respiratory assistance as discussed in the Dedo and Cook references cited in the final Office action. Reciting as an additional required step that which is inherently accomplished by the other steps when required is simply not mandatory, and in fact, will most likely be wrong and confusing. It would certainly be self defeating to require an *additional step* that is never separately performed. Doing so would mean that no one could ever infringe the claims. Additionally,

as stated above, it may not even be absolutely necessary. Only the actually necessarily performed steps must appear in the claims. The present claims comply with this requirement. As a result, the rejection of the claims on this basis must also be reversed.

Further, the specification need not use the exact language of later added claims. Citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ 2d 1111, 1116 (Fed.Cir. 1999, the Court in *Wang Laboratories Inc. v. Toshiba Corp*, 26 USPQ2d 1768, 1774 (Fed.Cir. 1993), stated:

> Although [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. . . . The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.
>
> * * * * *
>
> A patent specification is directed to one of ordinary skill in the art.

The ordinarily skilled artisan would clearly and unequivocally recognize from the present specification that the equipment of the figures show how the CPR of the present claims is carried out. Unquestionably, Applicants have met the statutory standard for both description and, certainly, enablement. Accordingly, the 35 U.S.C. 112, second paragraph, rejection of Claims 128-134, 145-156, 171-182, 198-209, 212, and 228-239 should also be reversed.

(g) The Rejection of Claims under 35 U.S.C. § 103(a)

In making the final, prior-art rejections, the examiner stated the following:

Claims 128 and 129 remain rejected under 35 U.S.C. 102(b) (sic) as being unpatentable over Dedo '579 in view of Cook (3,503,338).

6. As to claims 128 and 129, Dedo discloses a *device and inherently a method for CPR* treating patients comprising wrapping a belt/strap (24) with first and second opposite extremities around and in contact with a substantial majority of patient's chest (P) near said patient's sternum said belt extending around and being in contact with a major portion of the circumference of said chest, extending around and being in contact with the front sides and back of said chest, fastening/connecting to a power unit (71) said belt, placing an actuator (74) having first and second states in said first state to provide power from a power supply, such as a battery or outlet, to the power unit to repeatedly move the belt in a direction around the patient's chest (see Fig. 9). Dedo discloses that the belt is flexible but Dedo does not disclose that the belt is substantially inelastic. Cook discloses *a similar respiration appliance* having a compression belt (11) made from a substantially inelastic material (see Fig. 2 & Col. 2, lines 24-26). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to make Dedo's belt from a substantially inelastic material to improve the efficiency of the cheat compression process since the belt will not stretch substantially.

Claims 130-134, 228-239 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dedo in view of Cook '338 and in further view of Barkalow et al. (4,273,114).

7. As to Claims 130-134, Dedo and Cook disclose a *modified method of performing CPR* as described above (see discussion of claim 129). Dedo does not disclose that the method further includes defibrillating the torso of the patient undergoing resuscitation, detecting when the belt has place the patient's chest under maximal compression and inducing a defibrillating current at the time wherein two spaced outer chest surfaces are contacted with first and second electrodes. Barkalow discloses an apparatus *and inherently a method* of performing CPR that includes defibrillating the chest of a patient undergoing resuscitation, detecting when the belt has placed the patient's chest under maximal compression and inducing a defibrillating electric current at that time wherein two spaced outer chest surfaces are contacted with first and

second electrodes (48, 75)(see Fig. 6, ABSTRACT & Col. 8, lines 13-45). At the time of the invention, it would have been obvious to a person skilled in the art to combine Barkalow's step of simultaneous compression and defibrillation to *Dedo's CPR method* since the compression would shorten the path to the heart thereby reducing the power required to defibrillate the patient's heart.

8. As to claims 228-235 and 239, Dedo discloses a *modified* device and *inherently* a method for CPR treating patients comprising wrapping a belt/strap (24) with first and second opposite extremities around and in contact with a substantial majority of a patient's chest near said patient's sternum (P), said belt extending around and being contact with a major portion of the circumference of said chest, extending around and being in contact with the front sides and back of said chest and moving said belt in a direction to tighten the belt around the patient's chest to place the chest under compression with the belt extremities being moved substantially equally around the patient's left and right sides (see Fig. 9). Dedo discloses that the belt is flexible but Dedo does not disclose that the belt is substantially inelastic. Cook discloses *a similar respiration appliance* having a compression belt (11) made from a substantially inelastic material (see Fig. 2 & Col. 2, lines 24-26). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to make Dedo's belt from a substantially inelastic material to improve the efficiency of the chest compression process since the belt will not stretch substantially. Dedo does not disclose that the method further includes defibrillating the torso of the patient undergoing resuscitation, detecting when the belt has place the patient's chest under maximal compression and inducing a defibrillating current at the time wherein two spaced outer chest surfaces are contacted with first and second electrodes. Barkalow discloses an apparatus *and inherently a method* of performing CPR that includes defibrillating the chest of a patient undergoing resuscitation, detecting when the belt has placed the patient's chest under maximal compression and inducing a defibrillating electric current at that time wherein two spaced outer chest surfaces are contacted with first and second electrodes (48, 75) (see Fig. 6, ABSTRACT & Col. 8, lines 13-45). At the time of the invention, it would have been obvious to a person skilled in the art to combine Barkalow's step of simultaneous compression and defibrillation to

Dedo's CPR method since the compression would shorten the path to the heart thereby reducing the power required to defibrillate the patient's heart.

9. As to claims 236-238, *Dedo, Cook and Barkalow disclose a method for CPR as described above* (see discussion of claim 234). Dedo does not disclose that the belt tightener includes a fluid-pressure motor, a hydraulic motor, or a pneumatic motor. *The examiner takes Official Notice that the prior art includes medical devices that use a variety of motors for actuation of various components.* At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use any of an array of motors including those disclosed by the instant invention since they provide a readily usable and portable actuation force.

10. Claims 145, 146, 152-156, 171, 172, 178-182, 198, 199, 205-209 and 212 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dedo in view of Cook '388 and further in view of Szpur (5,407,418).

11. As to claims 145, 146, 152, and 153, Dedo discloses a device and *inherently* a method for CPR treating patients comprising wrapping a belt/strap (24) with first and second opposite extremities around and in contact with a substantial majority of a patient's chest (P), said belt extending around and being contact with a major portion of the circumference of said chest, extending around and being in contact with the front sides and back of said chest and fastening/connecting to an apparatus/power unit (72) said belt (see Fig. 9).). Dedo discloses that the belt is flexible but Dedo does not disclose that the belt is substantially inelastic. Cook discloses *a similar respiration appliance* having a compression belt (11) made from a substantially inelastic material (see Fig. 2 & Col. 2, lines 24-26). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to make Dedo's belt from a substantially inelastic material to improve the efficiency of the chest compression process since the belt will not stretch substantially. Dedo does not disclose providing a signal to a powered belt tightener to move the belt extremities in directions to tighten the belt around the patient's torso. Szpur discloses a similar mechanism that provides a timed application of force to a belt wherein the signal is provided to a belt tightener to move the belt to tighten around a user (see Col. 4, lines 18-47). At the time of the invention, it would have been obvious to a

person of ordinary skill in the art to substitute Dedo's belt tightening mechanism with Szpur's belt tightening mechanism such that Szpur's fittings (53 and 54 of hinge 40) are connected to Dedo's belt extremities 104 and 110 to allow for an electric motor controlled compression of the patient's torso since Szpur's mechanism allows for adjusting the time period of repeated compression and tightening of the belt substantially around the patient.

12. As to Claims 171, 171, 178, 179, 198, 199, 205, 206 and 312, *Dedo discloses a device and inherently a method for CPR treating patients* comprising wrapping a belt/strap (24) with first and second opposite extremities around and in contact with a substantial majority of a patient's chest (P), said belt extending around and being contact with a major portion of the circumference of said chest, extending around and being in contact with the front sides and back of said chest and fastening/connecting to the belt apparatus/power unit (72) (see Fig. 9). Dedo discloses that the belt is flexible but Dedo does not disclose that the belt is substantially inelastic. Cook discloses *a similar respiration appliance* having a compression belt (11) made from a substantially inelastic material (see Fig. 2 & Col. 2, lines 24-26). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to make Dedo's belt from a substantially inelastic material to improve the efficiency of the chest compression process since the belt will not stretch substantially. Dedo does not disclose that power is supplied in regular intervals to the power unit to repeatedly tighten the belt around the patient's torso and that the power unit is adapted to receive power from an electrical source via a cable/line. Szpur discloses a similar belt tightening mechanism having an electrical power unit that is adapted to automatically receive power from an electrical source via a cable/line (128) in regular intervals (see Fig. 3 & Col. 5, lines 9+). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to substitute Dedo's belt tightening mechanism with Szpur's belt tightening mechanism such that Szpur's fittings (53 and 54 of hinge 40) are connected to Dedo's belt extremities 104 and 110 to allow for an electric motor controlled compression of the patient's torso since Szpur's mechanism allows for adjusting the time period of repeated compression and tightening of the belt substantially around the patient's left and right sides.

13. As to claims 154-156, 180-182, and 207-209, *Dedo, Cook, Szpur disclose a modified method for CPR* as described above (see discussion of claims 152, 178 respectively). Szpur does not disclose that the belt tightener includes a fluid-pressure motor, a hydraulic motor, or pneumatic motor. *The examiner takes Official Notice* that the prior art includes medical devices that use a variety of motors for actuation of various components. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use any of an array of motors including those disclosed by the instant invention since they provide a readily usable and portable actuation force.

Claims 147-151, 173-177, 200-204 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dedo in view of Szpur, andCook '388 and further in view of Barkalow et al. (4,273,114).

14. As to claims 147-151, 173-177, 200-204, *Dedo, Cook, and Szpur disclose a modified method for CPR* as described above (see discussion of claims 145, 146, 171 and 712(sic)).). Dedo does not disclose that the method further includes defibrillating the torso of the patient undergoing resuscitation, detecting when the belt has place the patient's chest under maximal compression and inducing a defibrillating current at the time wherein two spaced outer chest surfaces are contacted with first and second electrodes. Barkalow discloses an apparatus *and inherently a method* of performing CPR that includes defibrillating the chest of a patient undergoing resuscitation, detecting when the belt has placed the patient's chest under maximal compression and inducing a defibrillating electric current at that time wherein two spaced outer chest surfaces are contacted with first and second electrodes (48, 75)(see Fig. 6, ABSTRACT & Col. 8, lines 13-45). At the time of the invention, it would have been obvious to a person skilled in the art to combine Barkalow's step of simultaneous compression and defibrillation to *Dedo's CPR method* since the compression would shorten the path to the heart thereby reducing the power required to defibrillate the patient's heart. (Pages 5 to 12, emphases added.)

* * * * *

As to the claims, applicant argues that Dedo does not disclose a CPR device that sits on the chest. Dedo discloses a respiratory assist device having a strap (24) that sits on the

> chest *wherein the cyclic compression forces provided by its belt could provide CPR*. In particular, Dedo discloses that the device is disposed to cover a lower region of the rib cage. Since a chest is defined by the human body enclosed by the ribs and sternum, Dedo's device is clearly disposed on the chest near the sternum. Examiner respectfully disagrees with Applicant in that Dedo would cause a backflow of blood toward the heart or that Dedo provides continuous pressure to the abdomen. Instead, Dedo, just like the instant invention, can compress the chest cyclically to assist respiration *and provide /CPR assistance*. Applicant also argues that Dedo's belt (46) has no active function but this is irrelevant since it is Dedo's strap that is tightened and released about a patient's chest to assist in respiration and the CPR process. Applicant also argues that there is no suggestion to combine Dedo with Szpur. As stated in the last office action, Szpur provides a timed application of force to tighten a belt around a user. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine Szpur's belt tightening mechanism with Szpur's (sic) strap (24) to allow for electrically controlled compression of a patient's chest. (Page 14, emphases added.)

All of the prior-art rejections use the following language or variants of it perhaps with other references for other features:

> *Dedo discloses a device and inherently a method for CPR treating patients* comprising wrapping a belt/strap (24) with first and second opposite extremities around and in contact with a substantial majority of patient's chest (P) near said patient's sternum said belt extending around and being in contact with a major portion of the circumference of said chest, extending around and being in contact with the front sides and back of said chest, fastening/connecting to a power unit (71) said belt, placing an actuator (74) having first and second states in said first state to provide power from a power supply, such as a battery or outlet, to the power unit to repeatedly move the belt in a direction around the patient's chest (see Fig. 9). Dedo discloses that the belt is flexible but Dedo does not disclose that the belt is substantially inelastic. *Cook discloses a similar respiration appliance*. (Emphasis added.)

This quotation (and the others like it or incorporating it in the final Office action) show a complete lack of comprehension of the process of CPR, its indications and uses, and the equipment necessary to carry it out. The suggestion that Dedo or Cook, alone or together teach any form of CPR, whether explicitly or inherently, simply cannot withstand even minimal scrutiny. As a consequence, it establishes the untenability of the rejection of the claims over the cited prior art and the patentability of Applicants' invention claimed in the present application.

The publications STANDARDS FOR CARDIOPULMONARY RESUSCITATION (CPR) AND EMERGENCY CARDIAC CARE (ECC) in the supplement to the Journal of the American Medical Association, dated February 18, 1974, Vol. 227, page 833, and TRANSTHORACIC RESISTANCE IN HUMAN DEFIBRILLATION, Circulation, 63, No. 3, 1981, both attached to the April 8, 2008, CLAIMS AND REFERENCES UNDER DISCUSSION FOR INTERVIEW OF APRIL 10, 2008, and again with the June 25, 2008, AMENDMENT, and here, clearly show the foible involved in citing the Dedo and Cook references (as well as Szpur) against the present application on CPR. On page 841, the *JAMA* supplement says:

> Part II. – Basic Life Support
>
> Basic life support is an emergency first aid procedure that consists of recognizing *respiratory and cardiac arrest* and starting the proper application of cardiopulmonary resuscitation to maintain life until a victim recovers sufficiently to be transported or until advance life support is available.
>
> * * * * *
>
> There must be a maximum sense of urgency in starting basic life support. The outstanding advantage of CPR is that it permits the earliest possible treatment of respiratory

> or cardiac arrest *by properly trained persons*. Optimally, only seconds should intervene between recognizing the need and starting treatment. (Page 841, emphases added.)

The flow diagram on page 842, labeled "Life Support Decision Tree [Unwitnessed arrest]" starts with a box containing the legend "UNCONSCIOUS VICTIM."

Both articles discuss the need for trained experts to provide CPR to a person with cardiac arrest. And, both point out the extreme condition of the patient. All of this unquestionably shows that the victim is extremely dire condition, in threat of immediate death, and may be considered virtually dead, but with the possibility of revival if treated immediately and absolutely correctly.

Dedo and Cook both show devices for providing a *slight* aid to respiration. ("expiration" in Dedo, col. 1, lines 5 and 6; "expel air from the lungs" in Cook, col. 1, lines 65 to 66.). Both Dedo and Cook talk of their devices finding use in persons suffering from the difficult breathing encountered in persons with emphysema. Both show the use of the Respirator Assist Device (Dedo) or Respiratory Apppliance (Cook) *by the affected individual himself or herself.*

The suggestion that the Dedo or Cook device teaches Applicants' method for the life-saving treating of cardiac or pulmonary arrest in an unconscious person simply ignores the nature of CPR, the condition of a person undergoing CPR, and the requirement for extreme, immediate, heroic life-saving procedures for the virtually deceased patient by expertly trained individuals. In fact, Cook has constructed his device so that the emphysemic patient can operate it *with a single hand.* (Cook, col. 1, lines 61 to 66.) The suggestion that both of these references inherently teach CPR is simply wrong.

In comparison, Barkalow et al., first cited in the May 15, 2006, Office action for other purposes as discussed above, show a CPR apparatus of a dramatically different type from that disclosed and claimed by Applicants. However, Barkalow et al do illustrate the maximal effort necessary to effectuate CPR in a person threatened with imminent death. Figure 8, in comparison to Figure 7, both of that patent, shows the dramatic compression on a person's chest required to achieve CPR. Simply stated, CPR must compress the heart. The respiratory assist devices of Dedo and Cook, had better not effectuate this result. This could well interfere with the operation of the individuals' hearts and cause these organs to stop working. Thus, contrary to the rejection of the claims, Dedo and Cook simply do not teach CPR either explicitly or inherently. The rejection based on these references must be reversed. This action is respectfully requested.

The act of combining Dedo and Cook with Barkalow et al. to show defibrillation of the heart under chest compression and under maximal compression, in particular, simply cannot withstand scrutiny. Initially, as discussed above, neither Dedo nor Cook teach, disclose, or suggest CPR in any form. Consequently, even combining either or both of them with Barkalow et al. for defibrillation cannot render Applicants' claimed invention obvious.

However, the suggested combination itself suffers from an even greater difficulty. As discussed above, Barkalow et al. incorporate (and are cited for) a defibrillation device in their pneumatic plunger-pump CPR device. However, the respiration devices (NOT CPR) of Dedo and Cook are *self-administered.* Making the suggested combination would result in a self-administered device by a person undertaking defibrillation. Stated in other

words, according to the rejection, an emphysemic patient will strap on the device of Dedo or Cook. He or she will then decide that perhaps he or she could use a little heart defibrillation and send an electric current *through his or her own heart muscle*. Clearly, this constitutes a totally unacceptable scenario. The same electrical current, if not handled properly, can very likely stop the heart and kill the individual. For these reasons, the combination of references proves totally unacceptable, and the rejection based on them should be overturned. This action is respectfully requested.

Combining the above reference of Dedo and Cook, with or without Barkalow et al., with Szpur stands on no better footing. Initially, as discussed at length above, and contrary to the assertions of the final Office action under appeal, neither Dedo nor Cook teach or suggest a belt-incorporating device for CPR. In fact, they simply cannot find use for that cited purpose.

Szpur shows a pulsating device for massaging and increasing the blood flow in a person's *foot* or other body part. It contains no suggestion that it can combine in any manner with the exhaling assisting devices of Dedo or Cook. Thus, all three of these, alone or together, do not teach or suggest CPR as taught and claimed by Applicants.

As discussed above, adding the defibrillating suggestion of Barkalow et al. to these references simply cannot produce Applicants' claimed method. The only additional feature consists of Szpur's foot (or other body part) massager. Again, allowing the patient to electrically shock his or her own heart constitutes a recipe for disaster, i.e., death. No CPR exists here either. As a consequence, the rejections over this combination of references should also be overturned.

(h) Conclusion

Applicants have properly disclosed and enabled their claimed invention that provides a significant improvement in the method of CPR. As shown above, the presently claimed invention covers a novel and improved method of CPR. The drawings clearly show the visible features of the method. The objection to the drawings in the final Office action appealed from basically requires that all features of the claimed, multi-step method be shown in a *single* drawing. That simply does not represent the standard. As discussed above, all features of the claimed process appear in the drawings.

As for the rejection of the specification under 35 U.S.C. § 132(a), the language of section (A) of the independent claims clearly appears in the drawings originally submitted with the original application as filed. As discussed above, the drawings form part of the originally filed specification, and thus support the alluded to claim language. Further, as also discussed above, the verbal portion of the specification also supports the claims under review.

The rejection of various claims under 35 U.S.C. § 112, first paragraph, also cannot stand. The features, recited in the final Office action, of defibrillating with the chest under compression, especially under maximal compression, constitute aspects of CPR well known in the art and receive a clear description in the specification as filed. This appears clear from the articles submitted by Applicants with their April 8, 2008, CLAIMS AND REFERENCES UNDER DISCUSSION FOR INTERVIEW OF APRIL 10, 2008, their June 25, 2008, AMENDMENT, and also attached to this paper. Stunningly, the reference

cited in the final Office action for the prior-art rejection of the claims containing this feature, Barkalow et al., needed no greater description of the defibrillation techniques. Unquestionably, Applicants have fulfilled their duty under the statute in this regard as well.

Similarly, the rejection under 35 U.S.C. § 112, second paragraph, lacks a sustainable basis. One skilled in the appropriate art recognizes the phrase "first and second states" as meaning, first, "on and off ", but may simply differentiate in terms of applied voltage as is standard in the relevant art of electromechanical devices. Or, it could well mean, as stated in the specification, the application and removal of pneumatic pressure. The statements in the final Office action of "it is not readily apparent how the belt is moved in a direction to tighten the belt around the patient's chest," "how the belt extremities are moved in directions to tighten the belt," and how the belt is moved in a direction to tighten the belt around a patient's chest," show a purposeful blindness to the application as filed, including especially its drawings. Lastly, the Applicants have properly disclosed and enabled their claimed invention that provides a significant improvement in the method of CPR.

The last two sentence of the rejection under 35 U.S.C. § 112, second paragraph, shows the necessity of reversing the final Office action rejection of the present application. Those sentences clearly say that the claims must separately recite "providing air/breath to the patient and that step is not included in the claims." However, as shown in the references cited by Applicants (attached here) and in the final Office action (Barkalow et al.), separately supplying air may or may not be required. It is, but only if the patient has stopped breathing. Further, the method recited in the claims must of necessity provide

respiratory assistance as discussed in the Dedo and Cook references cited in the final Office action. Adding the additional step recited in the final rejection can only be redundant and is simply not required. Only the actually necessarily performed steps must appear in the claims, not the optional or inherently and necessarily included results of the recited steps. The rejection of the claims on this basis must also be reversed.

Lastly, the prior art rejection under 35 U.S.C. § 103(a) requires converting both Dedo and Cook from something they clearly are, self-administered breathing assists (for example, in persons with emphysema) into CPR devices. This unwarranted conversion of the Dedo and Cook devices into something entirely different than what they disclose without any support or authority and contrary to the teaching of the extremely adverse consequences that could well follow if such were to occur is completely unwarranted. The rejection then compounds this error by suggesting that patient could employ this self administered equipment to supply "defibrillating" electric current to *his or her own heart.* Clearly, this rejection cannot withstand scrutiny and must be reversed.

In light of the above, the final Office action of April 21, 2009, finds no support in the law or the facts of this application. Accordingly, it cannot stand, and it should be reversed. Applicants respectfully request this action.

Applicant also encloses a form PTO-2038 in the amount of $245.00. This should serve to cover the fee of $245.00 for a two-month extension to file the present revised Appeal Brief, all for a small entity. Any required amount not paid by the enclosed PTO-2038 may be charged to Deposit Account 06-2135 of the undersigned attorney, and any

overpayment may be credited to that account.

Respectfully submitted,

Eugene F. Friedman
Attorney for Applicant
Reg, No. 25,627

Eugene F. Friedman
FRIEDMAN & FRIEDMAN, LTD.
Printers Square – Suite 710
780 South Federal Street
Chicago, Illinois 60605
(312) 922-8882
Facsimile (312) 922-1636
Dated: August 30, 2010

CERTIFICATE OF FAXING

I certify that this correspondence is being faxed to the Commissioner for Patents at facsimile number (571) 273-8300 on August 30, 2010.

Eugene F. Friedman

Appln. No. 10/633,938

(viii) CLAIMS APPENDIX

128. A method of CPR treating patients comprising:

(A) wrapping a belt, with first and second opposite extremities, around and in contact with a substantial majority of a patient's chest near said patient's sternum, said belt being in continuous contact with the patient's chest, including the front, sides, and a portion of the back of said patient's chest, said belt (1) extending around and being in contact with a major portion of the circumference of said chest, (2) extending around and being in contact with the front, sides and back of said chest, and (3) being substantially inelastic and flexible;

(B) fastening to a power unit said belt including any of said extremities of said belt not already fastened around said patient's chest;

(C) placing an actuator having first and second states in said first state; and

(D) with said actuator in said first state, providing power from a power supply to said power unit and moving said belt in a direction to tighten said belt around said patient's chest to perform CPR.

129. The method of Claim 128 further including periodically repeating steps (C) and (D).

130. The method of Claim 129 further comprising defibrillating the chest of said patient undergoing CPR.

131. The method of Claim 130 further including detecting when said belt has placed said patient's chest under compression, and, when said belt has placed said chest under compression, inducing a defibrillating electric current through said chest.

132. The method of Claim 131 further including detecting when said belt has placed said patient's chest about under maximal compression and, when said belt has placed said chest about under maximal compression, inducing said defibrillating electric current through said chest

133. The method of Claim 129 further including contacting two spaced outer chest surfaces with a first electrode and a second electrode.

134. The method of Claim 129 further including contacting two spaced outer chest surfaces with a first electrode and a second electrode.

145. A method of CPR treating patients comprising:

(A) wrapping a belt, with first and second opposite extremities, around and in contact with a substantial majority of a patient's chest near said patient's sternum, said belt being in continuous contact with the patient's chest, including the front, sides, and a portion of the back of said patient's chest, said belt (1) extending around and being in contact with a major portion of

the circumference of said chest, (2) extending around and being in contact with the front, sides and back of said chest, and (3) being substantially inelastic and flexible;

(B) fastening to an apparatus any of said extremities of said belt not already fastened to said apparatus;

(C) providing a particular signal to a powered belt tightener coupled to said belt extremities; and

(D) upon the receipt of said particular signal by said belt tightener, moving with said belt tightener, said belt extremities in directions to tighten said belt around said patient's chest to perform CPR.

146. The method of Claim 145 further including periodically repeating steps (C) and (D).

147. The method of Claim 146 further comprising defibrillating the chest of said patient undergoing CPR.

148. The method of Claim 147 further including detecting when said belt has placed said patient's chest under compression; and, when said belt has placed said chest under compression, inducing a defibrillating electric current through said chest.

149.. The method of Claim 148 further including detecting when said belt has placed said patient's chest about under maximal compression and, when said belt has placed said chest about under maximal compression, inducing said defibrillating electric current through said chest

150. The method of Claim 147 further including contacting two spaced outer chest surfaces with a first electrode and a second electrode.

151. The method of Claim 145 further including contacting two spaced outer chest surfaces with a first electrode and a second electrode.

152. The method of Claim 145 wherein said belt tightener, when said belt tightener moves said belt extremities in said directions, moves said belt in said directions to tighten said belt substantially equally around said patient's left and right sides.

153. The method of Claim 152 wherein said belt tightener includes an electric motor.

154. The method of Claim 152 wherein said belt tightener includes a fluid-pressure motor.

155. The method of Claim 154 wherein said belt tightener includes a hydraulic motor.

156. The method of Claim 154 wherein said belt tightener includes a pneumatic motor.

171. A method of CPR treating patients comprising:

(A) wrapping a belt, with first and second opposite extremities, around and in contact with a substantial majority of a patient's chest near said patient's sternum, said belt being in continuous contact with the patient's chest, including the front, sides, and a portion of the back of said patient's chest, said belt (1) extending around and being in contact with a major portion of the circumference of said chest, (2) extending around and being in contact with the front, sides and back of said chest, and (3) being substantially inelastic and flexible;

(B) fastening to a power unit said belt including any of said extremities of said belt not already fastened around said patient's chest;

(C) conveying power from a power supply to said power unit along a cable; and

(D) when said power reaches said power unit, moving said belt in a direction to tighten said belt around said patient's chest to perform CPR.

172. The method of Claim 171 further including periodically repeating steps (C) and (D).

173. The method of Claim 172 further comprising defibrillating the chest of said patient undergoing CPR.

174. The method of Claim 173 further including detecting when said belt has placed said patient's chest under compression; and, when said belt has placed said chest under compression, inducing a defibrillating electric current through said chest.

175. The method of Claim 174 further including detecting when said belt has placed said patient's chest about under maximal compression and, when said belt has placed said chest about under maximal compression, inducing said defibrillating electric current through said chest

176. The method of Claim 173 further including contacting two spaced outer chest surfaces with a first electrode and a second electrode.

177. The method of Claim 171 further including contacting two spaced outer chest surfaces with a first electrode and a second electrode.

178. The method of Claim 171 wherein said belt is moved in said direction to tighten said belt extremities substantially equally around said patient's left and right sides.

179. The method of Claim 178 wherein said power unit includes an electric motor.

180. The method of Claim 178 wherein said power unit includes a fluid-pressure motor.

181. The method of Claim 180 wherein said power unit includes a hydraulic motor.

182. The method of Claim 180 wherein said power unit includes a pneumatic motor.

198. A method of CPR treating patients comprising:

(A) wrapping a belt, with first and second opposite extremities, around and in contact with a substantial majority of a patient's chest near said patient's sternum, said belt being in continuous contact with the patient's chest, including the front, sides, and a portion of the back of said patient's chest, said belt (1) extending around and being in contact with a major portion of the circumference of said chest, (2) extending around and being in contact

with the front, sides and back of said chest, and (3) being substantially inelastic and flexible;

(B) fastening to a power unit said belt including any of said extremities of said belt not already fastened around said patient's chest;

(C) conveying power from a power supply to said power unit along a line; and

(D) when said power reaches said power unit, moving said belt extremities in directions to tighten said belt around said patient's chest to perform CPR.

199. The method of Claim 198 further including periodically repeating steps (C) and (D).

200. The method of Claim 199 further comprising defibrillating the chest of said patient undergoing CPR.

201. The method of Claim 200 further including detecting when said belt has placed said patient's chest under compression; and, when said belt has placed said chest under compression, inducing a defibrillating electric current through said chest.

202. The method of Claim 201 further including detecting when said belt has placed said patient's chest about under maximal compression and, when said belt has placed said chest about under maximal compression, inducing said defibrillating electric current through said chest

203. The method of Claim 200 further including contacting two spaced outer chest surfaces with a first electrode and a second electrode.

204. The method of Claim 198 further including contacting two spaced outer chest surfaces with a first electrode and a second electrode.

205. The method of Claim 198 wherein said belt is moved in said direction to tighten said belt extremities substantially equally around said patient's left and right sides.

206. The method of Claim 205 wherein said power unit includes an electric motor.

207. The method of Claim 205 wherein said power unit includes a fluid-pressure motor.

208. The method of Claim 207 wherein said power unit includes a hydraulic motor.

209. The method of Claim 207 wherein said power unit includes a pneumatic motor.

212. The method of Claim 198 wherein said power is conveyed from said power supply to said power unit along said line automatically and in regular periodic intervals.

228. A method of CPR treating patients comprising:

(A) wrapping a belt around and in contact with a substantial majority of a patient's chest near said patient's sternum, said belt being in continuous contact with the patient's chest, including the front, sides, and a portion of the back of said patient's chest, said belt (1) extending around and being in contact with a major portion of the circumference of said chest, (2) extending around and being in contact with the front, sides and back of said chest, and (3) being substantially inelastic and flexible;

(B) moving said belt in a direction to tighten said belt around said patient's chest and place said chest under compression to perform CPR;

(C) detecting when said belt has placed said patient's chest under compression; and

(D) when said belt has placed said chest under compression, inducing a defibrillating electric current through said chest.

229. The method of Claim 228 further including contacting two spaced outer chest surfaces with a first electrode and a second electrode.

230. The method of Claim 228 further including periodically repeating steps (B) through (D).

231. The method of Claim 228 further includes periodically repeating step (B).

232. The method of Claim 231 further including detecting when said belt has placed said patient's chest about under maximal compression and when said belt has placed said chest about under maximal compression, inducing said defibrillating electric current through said chest

233. The method of Claim 232 further including contacting two spaced outer chest surfaces with a first electrode and a second electrode.

234. The method of Claim 232 wherein, when said belt is moved in said direction to tighten said belt around said patient's chest and place said chest under compression, said belt extremities are moved substantially equally around said patient's left and right sides.

235. The method of Claim 234 wherein said belt is moved by an electric motor.

236. The method of Claim 234 wherein said belt is moved by a fluid-pressure motor.

237. The method of Claim 236 wherein said belt is moved by a hydraulic motor.

238. The method of Claim 236 wherein said belt is moved by a pneumatic motor.

239. The method of Claim 234 further including detecting when said belt has placed said patient's chest about under maximal compression and when said belt has placed said chest about under maximal compression, inducing said defibrillating electric current through said chest.

(ix) EVIDENCE APPENDIX

1. STANDARDS FOR CARDIOPULMONARY RESUSCITATION (CPR) AND EMERGENCY CARDIAC CARE (ECC) in the supplement to the Journal of the American Medical Association, dated February 18, 1974, Vol.. 227, page 833, a copy of which is attached.

2. TRANSTHORACIC RESISTANCE IN HUMAN DEFIBRILLATION, by R.E.. Kerber et al., *Circulation*, Vol. 63, No. 3, March 1981, a copy of which is attached.

Both of these references were previously submitted to the Patent and Trademark Office by facsimile on two separate occasions. The first occurred on April 8, 2008, when Applicants submitted their CLAIMS AND REFERENCES UNDER DISCUSSION FOR INTERVIEW OF APRIL 10, 2008. These two references were listed on page 14 of this paper and copies were attached. This paper was submitted for the purpose of facilitating the discussion to be held during the personal interview between the Examiners, one of the inventors, and the undersigned attorney which was scheduled for and took place on April 10, 2008.

The second submission occurred on June 25, 2008, when for the second time, Applicants faxed their AMENDMENT to the Office. Again, a copy of each article was attached to the paper. These articles received discussion on pages 64 and 65 of that AMENDMENT in much the same terms that appear in this APPEAL BRIEF.

Both of these articles constitute self-authenticating documents under Rule 902(6), Federal Rules of Evidence, "SELF-AUTHENTICATION – (6) Newspapers and

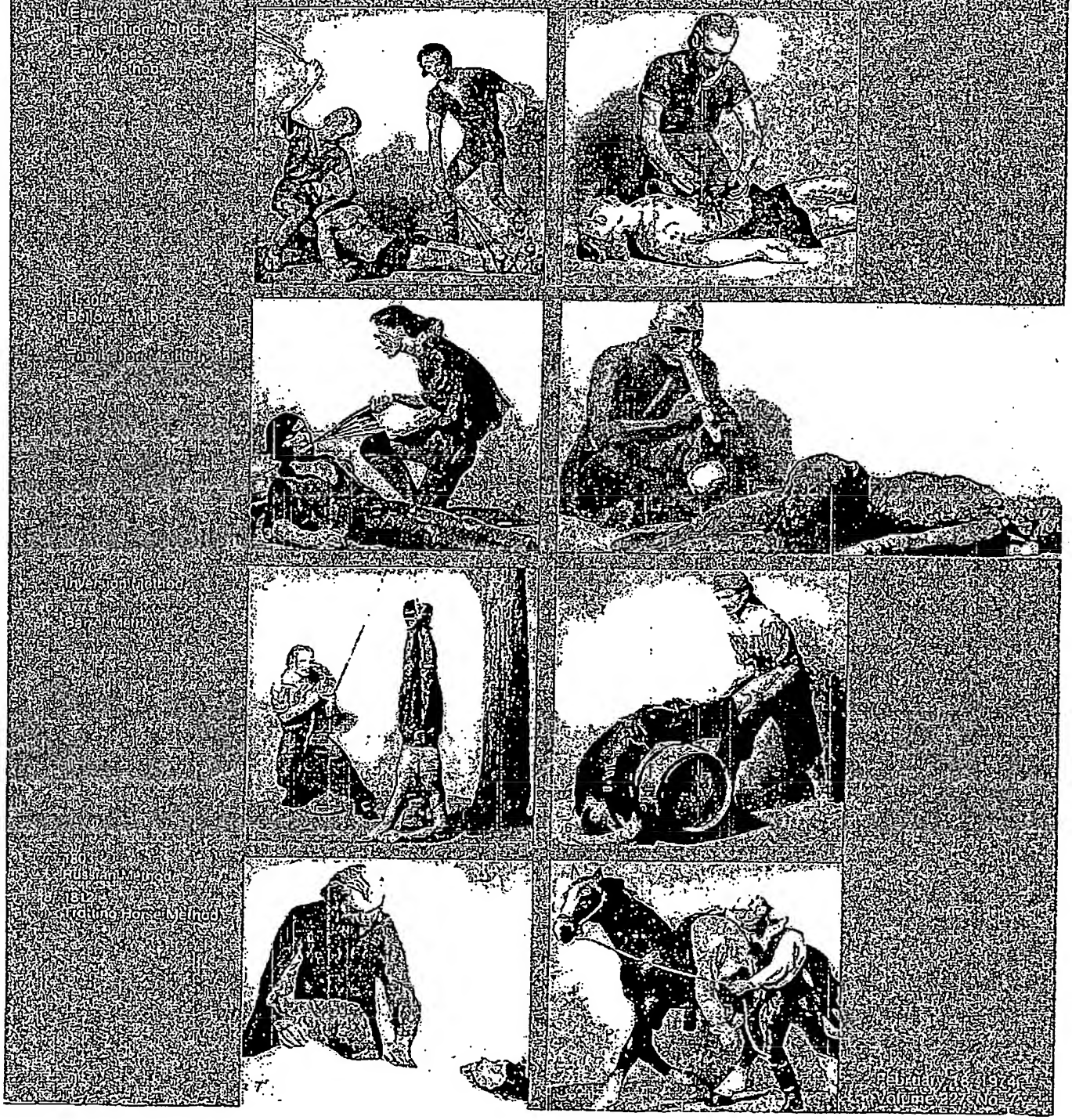
periodicals." The basis for self-authentication is that the reliability of periodical articles is very easily ascertained from publicly available copies of the periodicals themselves.

(viii) RELATED PROCEEDINGS APPENDIX

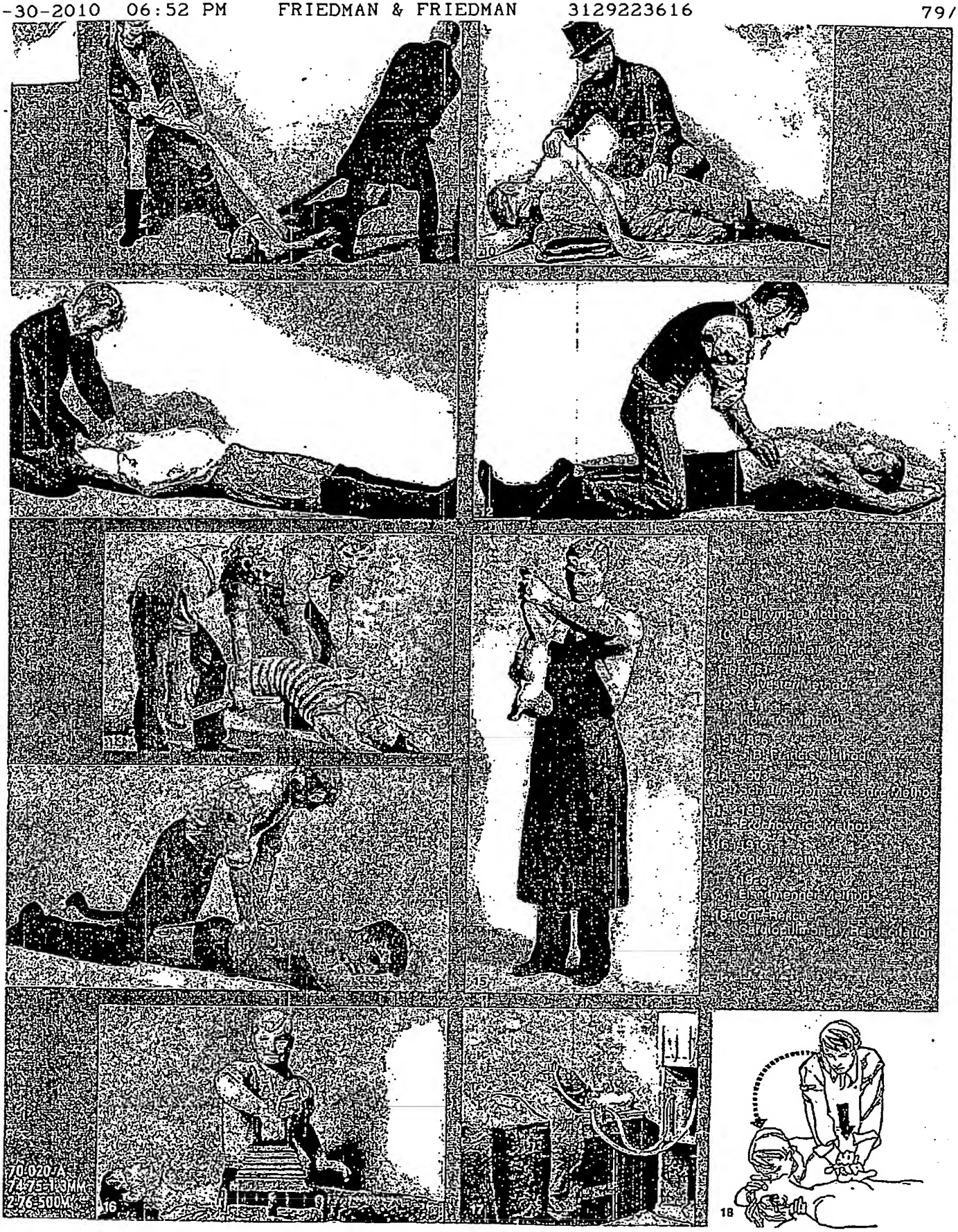
There were no related proceedings.

SUPPLEMENT TO
JAMA
THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION

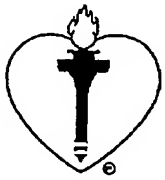
Standards for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC)



February 8, 1966
Volume 195, No. 6


70.020.7A
74.75-1.5M
276-500M

American Heart Association



and

National Academy of Sciences - National Research Council

These standards are the recommendations of the National Conference on Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC), May 16-18, 1973, Washington, DC, cosponsored by the American Heart Association and National Academy of Sciences-National Research Council. The Conference was supported in part by Contract No. NO1-HL-3-2960 from the National Heart and Lung Institute and the National Center for Health Services Research and Development, Department of Health, Education, and Welfare.

Publication of this supplement to JAMA was made possible by a grant from

ÅSMUND S. LÆRDAL

SUPPLEMENT TO

JAMA

THE JOURNAL of the American Medical Association

February 18, 1974
Vol 227, No 7 [Supplement]

THE JOURNAL is published weekly by the American Medical Association, 535 North Dearborn Street, Chicago, IL 60610. Phone 751-6000 (Area Code 312). Cable address "Medic" Chicago.

SUBSCRIPTION RATE—Price per annum in advance, including postage: Domestic, Canadian and Mexican, $23. Other foreign, $37. Price to medical students, interns, and residents, $8 in US, US possessions, Canada and Mexico.

Second-class postage paid at Chicago and additional mailing office. Address all subscription communications to Circulation Department.

CHANGE OF ADDRESS may be made by sending old address (as it appears on your Journal) and new address with zip code number. Instructions should state whether change is temporary or permanent. Allow six weeks for changeover.

ADVERTISING PRINCIPLES—Advertisements in this issue have been reviewed to comply with the principles governing advertising in AMA scientific publications. A copy of these principles is available upon request.

Contents

Historical Resuscitation Cover Illustrations

A fascinating variety of techniques for resuscitation of the dead and near-dead has been used by man down through the ages, even from the earliest of times. A number of these methods are shown on the front and back covers of this supplement.

Cover illustrations 1-17 were taken from scenes in a former exhibit in the Section on Medicine at the Museum of Science and Industry in Chicago. The exhibit was originally a gift to the museum by the Public Service Co. (of Northern Illinois). The figures were three dimensional, molded in wax, and stood about one foot high. They remained a popular exhibit at the museum until 1963, when they melted away and could not be resuscitated during a fire in the section of the building where the exhibit was housed.

1. Inflicting pain by whipping with stinging nettles, later supplemented by striking the skin with the hands and wet cloths, was considered helpful in restoring those apparently in deep sleep.

2. Warm ashes, hot water, and burning of dried animal excreta applied to the abdomen of patients were thought to be of value in restoring heat and life to the cold body.

3. Paracelsus was first to use common fireside bellows to introduce air into the lungs of apparently dead persons. Adaptations of this method were used throughout Europe for 300 years.

4. North American Indians attempted to revive apparently dead persons by blowing smoke into an animal bladder and therefrom into the victim's rectum. Called also "Dutch fumigation," it was introduced into England in 1767. The method was used successfully for years in American colonies.

5. This method was used in England, Europe, and America. Many cases of successful resuscitation from near-drowning are recorded. Pressure over chest aided in expelling air from lungs and inspiration resulted when pressure was removed.

6. This method, probably used before 1767, may still be seen along the waterfront. Barrel movement forward released pressure on victim's chest, allowing inspiration. Movement of barrel back caused the body's weight to compress the chest, inducing expiration.

7. Persons unconscious from cold or fumes or apparently dead were successfully resuscitated by burial. A modification was to bury a victim upright with his head and chest exposed. Water was dashed on his face.

8. This was used on Europe's inland waterways for resuscitation from near-drownings. The victim's own body, contacting the horse, compressed his chest, forcing out air. When he was bounced from horse's back, his chest expanded and air entered his lungs.

9. With a length of cloth encircling the chest, traction by two rescuers compressed the chest, forcing air from the lungs. Release of the pressure permitted the chest to expand, inducing inspiration.

10. This represents the first record of a victim laid prone, with chest elevated. The operator pulled the patient onto his side, held him momentarily, then let him roll back. Pressure on the back of the chest expelled air. Pressure was then released by turning the patient onto his side, causing inspiration.

11. With the victim on his back, arms above head, lung capacity is greater for inspiration; the arms are carried forward, folded on chest, and pressed to produce expiration. The tongue is held to keep the air passage open. This method is still in use.

12. Pressure is exerted on the back of the prone victim, with his chest raised, to expel water. He is then turned onto his back, with the operator straddling and exerting pressure on the upper abdomen and lower chest, causing expiration. Releasing the pressure causes inspiration.

13. Raising the victim by hyperextension of his body induces expiration; lowering him to the ground causes inspiration. This method is of little value, owing to the possibility of injury to the spine.

14. This simple method requires but one person. Pressure applied to the victim's back forces his abdomen against his diaphragm, compressing the lungs and causing expiration. Release of the pressure causes inspiration.

15. The inversion method is applied to a newborn baby. The pressure, created by squeezing the chest and by gravity, induces expiration; release of the chest compression lets air inflate the lungs for inspiration.

16. This device was strapped over the lower thorax and upper abdomen; by manual operation, the muscular walls were lifted by vacuum suction for inspiration; when pressure was exerted manually, air was forced from the lungs for expiration.

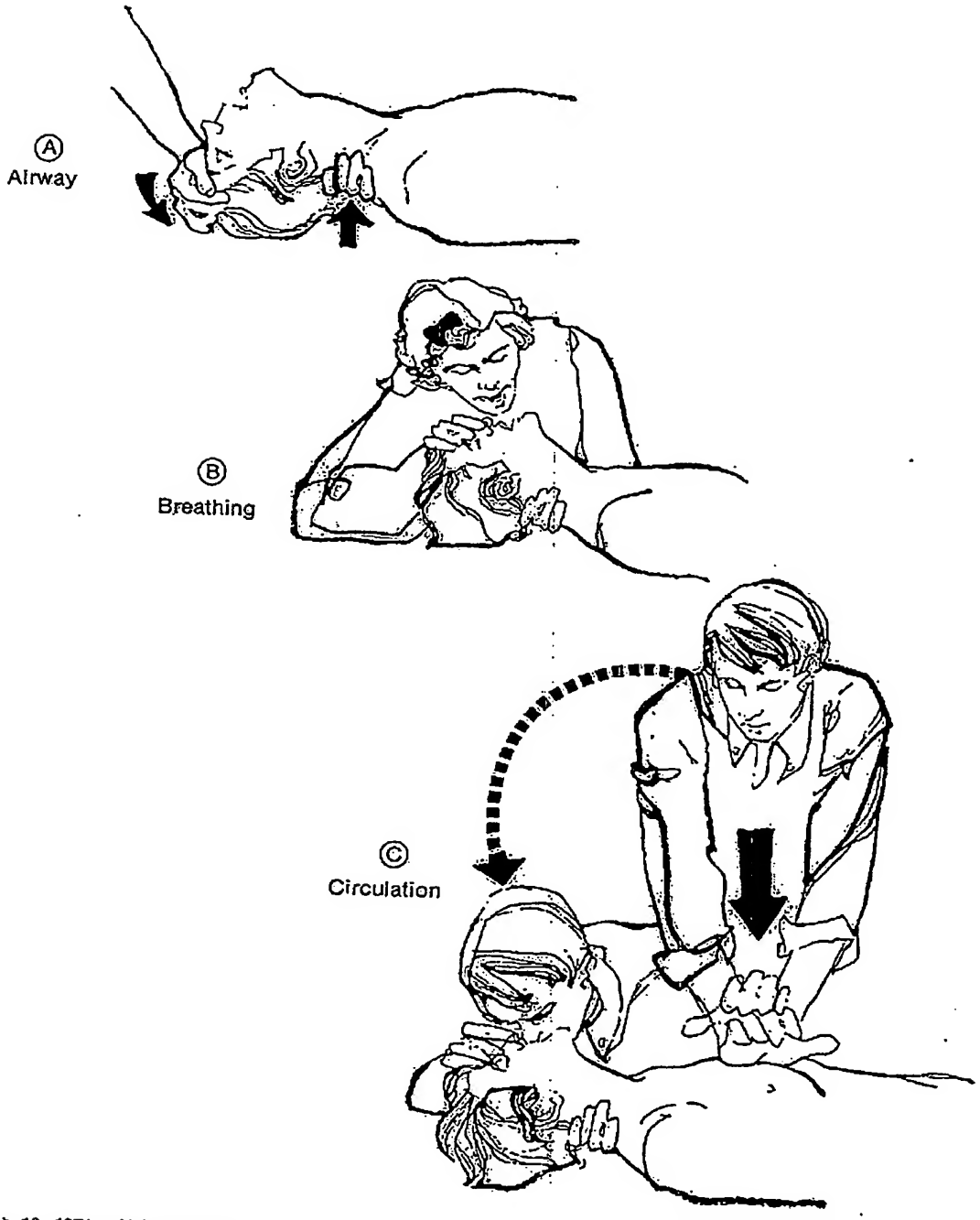
17. Air is pumped from an electrically driven diaphragm pump into pressure (expiration) and suction (inspiration) vessels, causing, within the dome on the patient's body, alternating positive and negative pressure to induce respiration in a natural manner.

18. The method for one-rescuer cardiopulmonary resuscitation as recommended in the standards given in this supplement.

Frontispiece

Cardiopulmonary Resuscitation (CPR)

(Basic Life Support)



Standards for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC)

At the National Conference on Standards for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC) held in May 1973, standards for CPR and ECC were developed and recommended. They relate to (1) recommended principles and techniques for basic and advanced life support, (2) CPR training and certification according to American Heart Association standards, (3) training of medical and allied health personnel, (4) the role of the American National Red Cross and other agencies in training the lay public, (5) the role of life support units in stratified systems of emergency cardiac care, and (6) medicolegal aspects of CPR and ECC. The complete conference proceedings will be published by the National Academy of Sciences.

THESE standards have been developed as a working guide for the proper training and performance of cardiopulmonary resuscitation and emergency cardiac care. They have been prepared by leading authorities and represent a consensus of many qualified persons from a variety of disciplines. However, the performance of cardiopulmonary resuscitation and emergency cardiac care is an art that is constantly changing and developing as the benefits of continuing experience and research become available, and the standards should serve to implement changes as required. They are in no way intended to limit new concepts or advances. Deviations from these standards may occur in certain situations not contemplated by the standards or where a trained clinician has a sound basis for his actions.

Part I.—Introduction

The American Heart Association and the National Academy of Sciences–National Research Council cosponsored a National Conference on Standards for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC) in Washington, DC, May 16-18, 1973. This Conference was conducted because of the changes that have occurred during the past several years. In May 1966, the National Academy of Sciences–National Research Council sponsored a Conference on Cardiopulmonary Resuscitation that recommended the training of medical, allied health, and professional paramedical personnel in cardiopulmonary resuscitation according to the standards of the American Heart Association.[8,10] Those recommendations resulted in widespread acceptance of cardiopulmonary resuscitation and training in the technique.

Since the 1966 meeting, cardiopulmonary resuscitation has become a part of the broader field of emergency cardiac care. This development has been influenced by the efforts and activities of many groups. Outstanding contributions have been made by the American Heart Association through its training materials and programs,[1-7] by the decisions of National Academy of Sciences–National Research Council committees and their publications,[8-15] by the reports of the Inter-Society Commission on Heart Disease Resources,[16-22] and by the recommendations and evaluations of government agencies,[23-29] professional medical

societies,[30-34] private groups,[35-39] and individuals.[40,41] These programs have been assisted financially and organizationally by federal agencies such as Regional Medical Programs, Health Services and Mental Health Administration, National Heart and Lung Institute, Department of Transportation, and by numerous state and local governing bodies, professional organizations, and rescue groups.

As a result of these activities, it has become increasingly apparent that a broad national program of life support measures is required to bring the benefits of cardiopulmonary resuscitation and emergency cardiac care to all segments of the public. This can be accomplished only by intensive public and professional programs.

These programs must

1. Provide education to increase awareness of the risk factors that may lead to heart attack, early warning signs and recognition of heart attack, and what to do in a cardiopulmonary emergency.
2. Eliminate patient and physician denial and reduce the time interval between onset of symptoms and the delivery of life support through the emergency medical care system.
3. Assure adequate training of large segments of the public in basic life support measures.
4. Generate integrated, community-wide stratified programs of emergency cardiac care as part of comprehensive emergency medical services.
5. Guarantee the availability and accessibility of an emergency care system for effective stabilization and treatment of emergency patients at the scene and during transportation by well-trained emergency medical technicians and other ambulance and rescue personnel.
6. Provide adequate life support units throughout all communities.
7. Standardize the roles of hospital staff and the adequacy of equipment and facilities in hospital emergency departments.

The Conference, accepting as a model program one that embodied all the above attributes, has created standards within this statement that will assist in promoting a national program of life support measures. Recommendations of the Conference are as follows:

1. Basic life support CPR training programs must be extended to the general public, starting with specific need groups such as policemen, firemen, lifeguards, rescue workers, high-risk-industry workers, and families of cardiac patients, and then expanded to include training of school children and other segments of the general public. The American National Red Cross, medical organizations, and other agencies concerned with lifesaving will participate in these programs.
2. Training in cardiopulmonary resuscitation and emergency cardiac care must be according to the standards of the American Heart Association. The association will continue to review, revise, and up-date the standards on the basis of scientific information and experience.
3. Certification of competency at various levels of life support must be based on nationally standardized curricula that include both written and performance tests.
4. Delivery of basic and advanced life support by highly trained personnel must be required for all life support units and hospitals on an integrated, stratified, community-wide basis.
5. These goals must be implemented by legislation and medicolegal action where needed, to ensure the delivery of effective cardiopulmonary resuscitation and emergency cardiac care to the entire population.

General Considerations

It has been estimated that about one million persons in the United States experience acute myocardial infarction each year. More than 650,000 die annually of ischemic heart disease. About 350,000 of these deaths occur outside the hospital, usually within two hours after the onset of symptoms. Thus, sudden death from heart attack is the most important medical emergency today. It seems probable that a large number of these deaths can be prevented by prompt, appropriate treatment. In addition, many victims who die as a result of such accidental causes as drowning, electrocution, suffocation, drug intoxication, or automobile accidents could be saved by the prompt and proper application of cardiopulmonary resuscitation and emergency cardiac care. This can best be assured by the victim's entry into an organized and effective system of emergency cardiac care.

Emergency cardiac care (ECC) is an integral part of a total, community-wide comprehensive system of emergency medical services (EMS) and should be integrated into the total system response capability for all types of life-threatening situations. The system must provide proper identification and appropriate action for all medical emergencies. However, the standards presented here concern themselves only with the principles and concepts of emergency cardiac care.

Emergency Cardiac Care

In this statement, emergency cardiac care includes all the following elements:

1. Recognizing early warning signs of heart attacks, preventing complications, reassuring the victim, and moving him to a life support unit without delay.
2. Providing immediate basic life support at the scene, when needed.
3. Providing advanced life support as quickly as possible.
4. Transferring the stabilized victim for continued cardiac care.

Emergency transportation alone, *without life support*, does not constitute emergency cardiac care. Although transportation is an important aspect, the major emphasis of ECC is life support through stabilization of the victim *at the scene* of the life-threatening emergency. Stabilization must be maintained during transport of the victim to the site of continuing cardiac care.

Within the definition of emergency cardiac care there are two other important concepts that must be clarified—basic life support and advanced life support.

Basic Life Support is an emergency first aid procedure that consists of the recognition of airway obstruction, respiratory arrest and cardiac arrest, and the proper application of cardiopulmonary resuscitation (CPR). CPR consists of opening and maintaining a patent airway, providing artificial ventilation by means of rescue breathing, and providing artificial circulation by means of external cardiac compression.

Advanced Life Support is basic life support plus use

of adjunctive equipment, intravenous fluid lifeline (infusion), drug administration, defibrillation, stabilization of the victim by cardiac monitoring, control of arrhythmias, and postresuscitation care. Also it includes establishing necessary communication to assure continuing care, and maintaining monitoring and life support until the victim has been transported and admitted to a continuing care facility. Advanced life support requires the general supervision and direction of a physician who assumes responsibility for the unit. It must have adequate communications on a 24-hour-per-day basis. This may necessitate appropriate legislation or standing orders for implementation.

To be effective, emergency cardiac care should be an integrated part of a total community-wide emergency care and communication system. It is to be based on local community needs and resources and be consistent with state and national policies. The success of such a community-wide system requires multijurisdictional participation and planning to ensure operational, as well as equipment, compatibility within that system and between adjacent systems. The initial planning of a community-wide system should be under the direction of a local community advisory council on emergency services charged with the responsibility of assessing community needs and resources, defining priorities, and planning to meet those needs. Critical evaluation of operating policies, procedures, statistics, and case reports must be a continuing responsibility of state or local governments or the council. Such an evaluation should provide the basis for modification and evolution of the system.

It is well recognized that the emergency cardiac care segment of a community-wide emergency system is best provided through a stratified system of coronary care.[19] This stratified system has three levels:

Level 1: Emergency Life Support Units
(a) Life Support Units
(1) Basic
(2) Advanced
(b) Mobile Life Support Units
(1) Basic
(2) Advanced
Level 2: Coronary Care Units
Intermediate Care Units
Level 3: Regional Reference Centers.

The standards recommended within this statement are concerned only with the first level, *emergency life support units*. Components such as public education, professional education, and emergency medical communication are essential parts of the total emergency system.

Public Education.—The greatest risk of death from heart attack lies in the first two hours after onset. The potential victim must first be educated to recognize the usual manifestations of heart attack—persistent chest-shoulder-arm pain, sweating, nausea-vomiting, palpitation, fatigue. He then must know how to gain access to the emergency medical system. The fastest way for an emergency medical team to respond is through the use of a universal emergency telephone number, such as 911. Once this number is established, it must be promoted through an educational program so that it will be used.

Each individual should have a well-formulated plan of action for use in an emergency. This plan will be based on the plan of action optimal for his own community. In some cases, this means that a physician should be called first, and, if he is not immediately available, the victim should proceed without delay to an emergency department or a facility with life support capability.

When symptoms suggest an acute heart attack, the Conference recommends that a mobile life support unit be summoned to reduce the elapsed time from the onset of symptoms to entry into an emergency medical services (EMS) system.

Professional Education.—Physicians must be aware of the emergency medical system in their own communities. Their actions should reflect the knowledge that most cardiac fatalities occur outside the hospital, and that every effort must be made to reduce the delay between the initial symptoms and the victim's entry into an effective emergency care system. The physician should be aware of possible delays and avoid them.

Physician competence in CPR must be assured, and he should formulate a plan of action for emergency cardiac situations occurring in his office, in patients' homes, and elsewhere in the community.

Emergency Medical Communications.—Emergency medical communications is a vital element that must be integrated into any system of emergency medical services for it to function effectively. An adequate communication network for an ECC response is but one facet of total emergency medical services, but the communications system that supports emergency cardiac care also should support emergency medical service as a whole.

The communications system will help preserve life and minimize morbidity at the scene, during transit, and in the hospital emergency department. There should be careful coordination of equipment and frequencies, including subcarriers for telemetry, to facilitate both compatibility of subsystems at their interface and effective regionalization in the future.

Agreements for sharing communication channels and other forms of coordination are necessary. Emergency medical communications should be integrated into the emergency system and coordinated with such other agencies as fire, police, highway patrol, Coast Guard, and Military Assistance to Safety and Traffic.

The emergency medical system should provide for central receipt of all emergency calls and central dispatching of all elements of that system, depending on the nature of the emergency, geographic location, capability of the rescuing units, and other emergencies in progress. The central emergency medical communication center must have full knowledge of emer-

gency care systems, their composition, their disposition, and all activities, as well as medical capabilities and census of each hospital in the area. The central dispatchers also must be issued medical guidelines to help them determine the appropriate medical facility to care for each medical emergency.

Personnel of the central dispatching agency should receive special training in methods of rapid and complete questioning to determine the medical problem. They must be able to distinguish quickly the medical requirements for each type of emergency situation and follow the medical guidelines as to the most appropriate available receiving facility. In some communities, multilingual dispatchers will be required.

The communication network should be able to link each of the following to each other by means of two-way voice communications via the telephone, radio, or other means: the rescuer at the scene, the rescue vehicle, all hospitals that might receive the victim, and advisory medical personnel. Telephone-to-radio circuit interconnection, or telephone patch, should be considered as one means of extending the EMS communication system, including remote consultation, to any person or facility within reach of a telephone.

In many instances, two-way communication may be augmented by electrocardiogram telemetry. Telemetry methods and telemetry techniques must be standardized within health care delivery regions to assure that all systems within a region are compatible. It is vital that the rescuer be able to communicate directly with the EMS physician or specially designated nurse who can advise him regarding definitive medical theory. The communications network should ensure that the receiving station or hospital is notified of the impending arrival of the victim, the nature of his problem, and his general medical condition.

Conference Recommendations.—Conference participants reported that the present rules and regulations of the Federal Communications Commission (FCC) frustrate the achievement of a comprehensive communication system. Adequate emergency medical service communication channels are as vital to the public as the communication channels used by police and fire services. The Conference Committees recommend that the FCC establish an emergency medical radio service that would provide sufficient spectrum space and adequate protection from interference by other services. Furthermore, the frequencies should be freely available for a variety of emergency medical applications, eg, medical voice supervision, continuous and intermittent telemetry, and relay from fixed and mobile transmitters. This freedom is necessary to ensure the growth of effective emergency medical service programs.

Role of the American Heart Association

In 1963, the American Heart Association established a Committee on Cardiopulmonary Resuscitation. This was expanded in 1971 to a Committee on Cardiopulmonary Resuscitation and Emergency Cardiac Care. The activities of this Committee have established for it a multiplicity of continuing roles in these areas. The Conference recognizes that these roles concern basic life support, advanced life support, and all aspects of emergency cardiac care, and that they have evolved into the following Committee charges:

1. To establish and revise standard concepts and techniques periodically for basic and advanced life support as related to cardiopulmonary resuscitation and stratified emergency cardiac care.
2. To establish standards for training and retraining in basic and advanced life support.
3. To establish standards for training aids and materials.
4. To develop and distribute training materials.
5. To collaborate with other national medical and allied health organizations in establishing and promoting training programs in basic and advanced life support for medical and allied health groups.
6. To train and certify instructor-trainers and instructors for various organizations such as American National Red Cross, YMCA, Medical Self Help, fire and rescue departments, police departments, ambulance emergency medical technicians, lifeguards, Scouts, Department of Defense, and other interested groups, which then will be responsible for CPR instruction of key personnel and trainees for their various groups at the community level according to the American Heart Association training standards.
7. To act, as a catalyst at both the local and national levels to motivate and stimulate the development of regional planning councils, which are required for the development of stratified emergency cardiac care systems.
8. To develop and implement a simultaneous, coordinated, large-scale public education program at the national and local levels in the areas of CPR, early warning signs, and risk factors, as related to development and use of stratified emergency cardiac care systems. To help meet the needs of public response, it is planned that these programs will be coordinated with the American National Red Cross and other first aid and medical agencies.
9. To direct intensive professional education efforts to physicians to increase their awareness of the necessity for early entry of patients into (a) monitored cardiac care systems and (b) precoronary care areas.
10. To promulgate criteria at a national level to aid in decisions regarding when basic life support should not be instituted, when advanced life support should not be instituted, and when basic or advanced life support may be terminated.
11. To evolve practical guidelines for developing stratified cardiac care systems that are capable of implementation at the community level.
12. To disseminate criteria for American Heart Association affiliates and chapters to certify persons in basic and advanced life support according to nationally standardized course content and testing.
13. To disseminate such information to the medical community as (a) to date, there has not been a successful legal action against a person who has given CPR in good faith, (b) in general, medical practice acts exempt nonphysicians who are acting in an emergency situation, and (c) through the use of the CPR techniques where recommended, a large number of cardiac arrest victims have been successfully resuscitated at locations outside of hospitals and many long-term survivors have returned to full and productive lives.
14. To assist in the creation of effective "Good Samaritan" coverage for physicians, nurses, professional allied health personnel, and nonmedical personnel performing basic or advanced life support in good faith either inside or outside any life support unit.

Part II.—Basic Life Support

Basic life support is an emergency first aid procedure that consists of recognizing respiratory and cardiac arrest and starting the proper application of cardiopulmonary resuscitation to maintain life until a victim recovers sufficiently to be transported or until advanced life support is available. This includes the A-B-C steps of cardiopulmonary resuscitation:

A. Airway B. Breathing	artificial ventilation	cardiopulmonary resuscitation
C. Circulation	artificial circulation	

These steps always should be started as quickly as possible. They are performed in the order shown above (also shown in the frontispiece and in Fig 1, Life Support Decision Tree) except in special circumstances such as: (*a*) in monitored patients or (*b*) in witnessed cardiac arrests. When cardiac arrest occurs in the monitored patient and trained personnel and defibrillators are available immediately, a precordial thump and/or advanced life support procedures should be instituted without delay. In a witnessed cardiac arrest, the A-B-C sequence should include use of a precordial thump. (See "Precordial Thump," page 847.)

There must be a maximum sense of urgency in starting basic life support. The outstanding advantage of CPR is that it permits the earliest possible treatment of respiratory arrest or cardiac arrest by properly trained persons. Optimally, only seconds should intervene between recognizing the need and starting treatment.

Indications for basic life support are:

1. Respiratory arrest and
2. Cardiac arrest. Cardiac arrest can result from:
   (a) cardiovascular collapse (electromechanical dissociation)
   (b) ventricular fibrillation, or
   (c) ventricular standstill (asystole).

In cases of collapsed or unconscious persons, the adequacy or absence of breathing and circulation must be determined immediately. If breathing alone is inadequate or absent, rescue breathing may be all that is necessary. If circulation is also absent, artificial circulation must be started in combination with rescue breathing. The methods of recognizing adequacy or absence of breathing or circulation and the recommended techniques for performing artificial ventilation and artificial circulation are presented below. Their proper stepwise sequence is detailed in the Life Support Decision Tree (Fig 1).

Artificial Ventilation

Opening the airway and restoring breathing are the basic steps of artificial ventilation. The steps can be performed quickly under almost any circumstance and without adjunctive equipment or help from another person. They constitute emergency first aid for airway obstruction and respiratory inadequacy or arrest.

Respiratory inadequacy may result from an obstruction of the airway or from respiratory failure. An obstructed airway is sometimes difficult to recognize until the airway is opened. At other times, a partially obstructed airway is recognized by labored breathing or excessive respiratory efforts, often involving accessory muscles of respiration, and by soft tissue retractions of the intercostal, supraclavicular, and suprasternal spaces. Respiratory failure is characterized by minimal or absent respiratory effort, failure of the chest or upper abdomen to move, and inability to detect air movement through the nose or mouth.

Airway.—The most important factor for successful resuscitation is immediate opening of the airway. This can be accomplished easily and quickly by tilting the victim's head backward as far as possible. Sometimes this simple maneuver is all that is required for breathing to resume spontaneously. To perform the head tilt, the victim must be lying on his back. The rescuer places one hand beneath the victim's neck and the other hand on his forehead. He then lifts the neck with one hand and tilts the head backward by pressure with his other hand on the forehead. This maneuver extends the neck and lifts the tongue away from the back of the throat. Anatomical obstruction of the airway caused by the tongue dropping against the back of the throat thereby is relieved. The head must be maintained in this position at all times. (See Fig 2.)

The head tilt method is effective in most cases. If head tilt is unsuccessful in opening the air passage adequately, additional forward displacement of the lower jaw—jaw thrust—may be required. This can be accomplished by a triple airway maneuver in which the rescuer places his fingers behind the angles of the

Life Support Decision Tree
[Unwitnessed arrest]

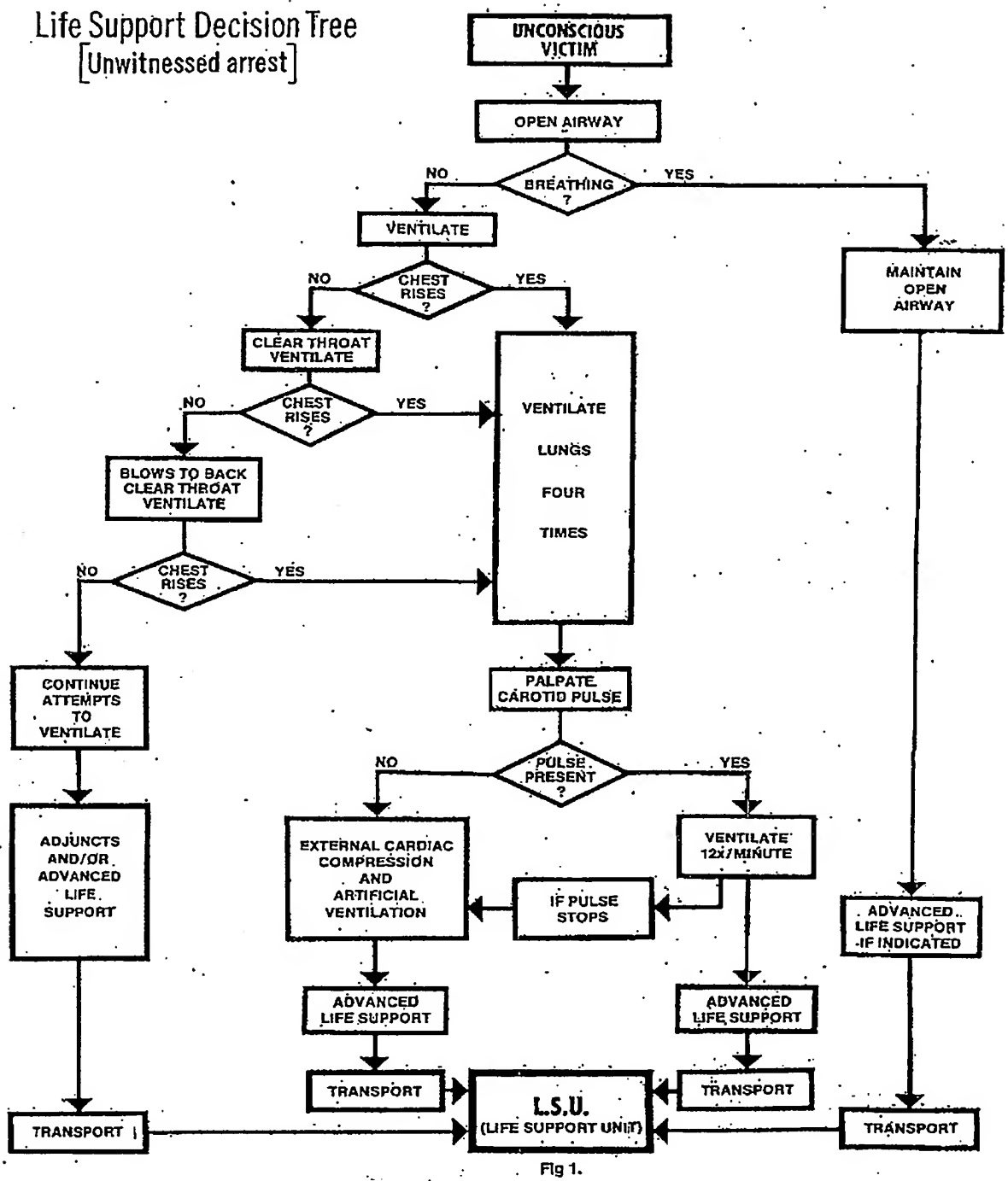


Fig 1.

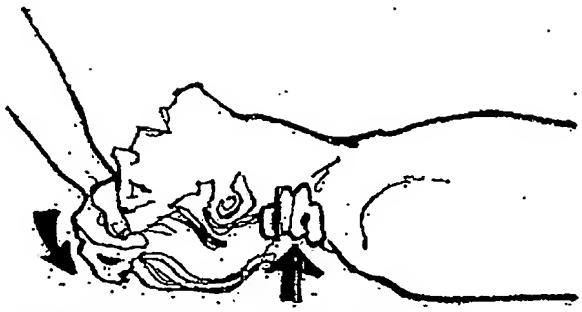


Fig 2.—Head tilt method of opening airway

victim's jaw and (1) forcefully displaces the mandible forward while (2) tilting the head backward and (3) using his thumbs to retract the lower lip to allow breathing through the mouth as well as through the nose. The jaw thrust is performed best from a position at the top of the victim's head.

However, if the victim does not resume spontaneous breathing, the rescuer must move to the victim's side to perform mouth-to-mouth or mouth-to-nose ventilation. Several variations of the jaw thrust may be used. When using jaw thrust for mouth-to-mouth ventilation, the rescuer must keep the victim's mouth open with his thumbs and seal the nose by placing his cheek against it. However, this is more difficult to teach and practice on manikins, and more difficult and tiring to perform on victims than the head tilt method. For mouth-to-nose ventilation with jaw thrust, the rescuer uses his cheek to seal the victim's mouth and does not retract the lower lip with his thumbs. Such special details of performance and the problems associated with manikin practice limit use of jaw thrust techniques to specially trained personnel.

Breathing.—If the victim does not promptly resume adequate spontaneous breathing after the airway is opened, artificial ventilation, sometimes called rescue breathing, must be started. Mouth-to-mouth breathing and mouth-to-nose breathing are both types of artificial ventilation.

To perform mouth-to-mouth ventilation, the rescuer uses his hand behind the victim's neck to maintain the head in a position of maximum backward tilt. He pinches the victim's nostrils together with the thumb and index finger of his other hand, which also continues to exert pressure on the forehead to maintain the backward head tilt. The rescuer then opens his mouth widely, takes a deep breath, makes a tight seal with his mouth around the victim's mouth and blows into the victim's mouth. He then removes his mouth and allows the victim to exhale passively, watching the victim's chest fall. This cycle is repeated *once every five seconds* as long as respiratory inadequacy persists.

Adequate ventilation is ensured on every breath by the rescuer

1. Seeing the chest rise and fall
2. Feeling in his own airway the resistance and compliance of the victim's lungs as they expand
3. Hearing and feeling the air escape during exhalation. The initial ventilatory maneuver should be *four quick, full, breaths* without allowing time for full lung deflation between breaths. (See Fig 8.)

In some cases, mouth-to-nose ventilation is more effective than mouth-to-mouth ventilation. The former is recommended when it is impossible to open the victim's mouth, when it is impossible to ventilate through his mouth, when the victim's mouth is seriously injured, when it is difficult to achieve a tight seal around his mouth, and when, for some other reason, the rescuer prefers the nasal route.

For the mouth-to-nose technique, the rescuer keeps the victim's head tilted back with one hand on the forehead and uses the other hand to lift the victim's lower jaw. This seals the lips. The rescuer then takes a deep breath, seals his lips around the victim's nose and blows in until he feels the lungs expand. The rescuer removes his mouth and the victim is allowed to exhale passively. The rescuer can see the chest fall when the victim exhales. When mouth-to-nose ventilation is used, it may be necessary to open the victim's mouth or separate his lips to allow the air to escape during exhalation because the soft palate may cause nasopharyngeal obstruction. This cycle should be repeated approximately every five seconds.

Direct mouth-to-stoma artificial ventilation should be used for persons who have had a laryngectomy. They have a permanent stoma that connects their trachea directly to the skin. It is recognized as an opening at the front of the base of the neck. Neither head tilt nor jaw thrust maneuvers are required for mouth-to-stoma resuscitation. For a patient with a temporary tracheostomy tube in his airway, it is usually necessary for the rescuer to seal the victim's mouth and nose with his hand or a tightly fitting face mask to prevent leakage of air when the rescuer blows into the tracheostomy tube. This problem can be prevented if the tracheostomy tube is provided with an inflatable cuff.

No adjuncts are required for effective rescue breathing; so artificial ventilation should never be delayed to obtain or apply adjunctive devices.

Infants and Children.—Opening the airway and performing artificial ventilation are essentially the same for children as for adults. There are some differences, however. For infants and small children, the rescuer covers both the mouth and nose of the child with his mouth and uses small breaths with less volume to inflate the lungs *once every three seconds*. The neck of an infant is so pliable that forceful backward tilting of the head may obstruct breathing passages. Therefore, the tilted position should not be exaggerated.

Accident Cases.—In accident cases, it is imperative that caution be used to avoid extension of the neck when there is a possibility of neck fracture. A fractured neck should be suspected in diving or automobile accidents when the victim has lacerations of the

Fig 3.—Mouth-to-mouth resuscitation

face and forehead. If a fracture is suspected, all forward, backward, lateral, or turning movement should be avoided. To open the airway, a modification of the jaw thrust maneuver described above should be used. In this variation, the rescuer places his hands on either side of the victim's head so the head is maintained in a fixed, neutral position without the head extended. The index fingers should then be used to displace the mandible forward without tilting the head backward or turning it to either side (modified jaw thrust). If required, artificial ventilation usually can be provided in this position. If this is unsuccessful, the head should be tilted back very slightly and another attempt made to ventilate, using the modified jaw thrust maneuver.

Foreign Bodies.—The rescuer should not look for foreign bodies in the upper airway unless their presence is known or strongly suspected. The first effort to ventilate the lungs will determine whether an airway obstruction is present. If the first attempts to ventilate are unsuccessful despite properly opening the airway and providing an airtight seal around the mouth, an attempt should be made immediately to clear the airway with the fingers. The victim should be rolled onto his side, with the rescuer's knee placed under his shoulder. The victim's mouth then is forced open with the thumb and index crossed-finger technique. The rescuer runs his index finger or index and middle fingers down the inside of the victim's cheek toward the base of the tongue, deep into his throat. The rescuer's fingers are moved across the back of the victim's throat with a sweeping motion. Repeated attempts may be required. Where skilled, advanced life support personnel and equipment are available, direct laryngoscopy may permit the foreign body to be removed.

Larger foreign bodies frequently can be extricated by these finger maneuvers. If the rescuer is unable to dislodge the foreign body, or if it is impacted below the epiglottis, the victim should be rolled onto his side toward the rescuer, who then delivers sharp blows with the heel of his hand between the victim's shoulder blades. Further attempts at clearing the airway then should be made. If unsuccessful, there should be repeated efforts at mouth-to-mouth resuscitation, blows to the back, and probing the upper airway with the fingers. A small child having airway obstruction should be quickly picked up and inverted over the arm of the rescuer while the blows are being delivered between the child's shoulder blades.

If all of these maneuvers fail, emergency cricothyroid puncture and insertion of a 6 mm tube have been recommended for adults. However, this requires appropriate instruments and training and must be regarded as an advanced life support technique.

Gastric Distension.—Artificial ventilation frequently causes distension of the stomach. This occurs most often in children, but it is not uncommon in adults. It is most likely to occur when excessive pressures are used for inflation or if the airway is obstructed. Slight gastric distension may be disregarded. However, marked distension of the stomach may be dangerous because it promotes regurgitation, and it reduces lung volume by elevating the diaphragm. Several cases of gastric rupture resulting from overdistension have been reported. Obvious gross distension should be relieved whenever possible. In the unconscious victim, this can be accomplished without adjuncts by using one hand to exert moderate pressure over the victim's epigastrium between the umbilicus and the rib cage. To prevent aspiration of gastric contents during this maneuver, the victim's head and shoulders should be turned to one side.

Artificial Circulation (External Cardiac Compression)

When sudden, unexpected cardiac arrest occurs, all of the A-B-C's of basic life support are required in rapid succession. This includes both artificial ventilation and artificial circulaton (external cardiac compression). Cardiac arrest is recognized by pulselessness in large arteries in an unconscious victim having a death-like appearance and absent breathing. The status of the carotid pulse should be checked as quickly as possible when cardiac arrest is suspected. In an unwitnessed cardiac arrest, the rescuer first opens the airway and quickly ventilates the lungs four times. He then maintains the head tilt with one hand on the forehead, and with the tips of the index and middle fingers of the other hand, gently locates the victim's larynx and slides his fingers laterally into the groove between the trachea and the muscles at the side of the neck where the carotid pulse can be felt. The pulse area must be felt gently, not compressed.

There are a number of reasons for recommending

palpation of the carotid pulse rather than other pulses. First, the rescuer already is at the victim's head to perform artificial ventilation and the carotid pulse is in the same area. Second, the neck area generally is accessible immediately, without removal of any clothing. Third, the carotid arteries are central and sometimes these pulses will persist when more peripheral pulses are no longer palpable. Trainees should practice palpation of the carotid pulse during classes. In hospital situations, palpation of the femoral artery is an acceptable option to use instead of the carotid artery. It is not practical to feel the carotid pulse in infants and small children. Instead, the rescuer's hand should be placed gently over the precordium to feel the apical beat.

Absence or questionable presence of the pulse is the indication for starting artificial circulation by means of external cardiac compression. External cardiac compression consists of the rhythmic application of pressure over the lower one half of the sternum, but *not over the xiphoid process.* The heart lies slightly to the left of the middle of the chest between the lower sternum and the spine. Intermittent pressure applied to the sternum compresses the heart and produces a pulsatile artificial circulation. During cardiac arrest, properly performed external cardiac compression can produce systolic blood pressure peaks of over 100 mm Hg, but the diastolic pressure is zero and the mean pressure seldom exceeds 40 mm Hg in the carotid arteries. The carotid artery blood flow resulting from external cardiac compression on a cardiac arrest victim usually is only one quarter to one third of normal.

External cardiac compression always must be accompanied by artificial ventilation. Compression of the sternum produces some ventilation, but the volumes are insufficient for adequate oxygenation of the blood. Therefore, artificial ventilation is *always* required when external cardiac compression is used.

Technique for External Cardiac Compression.—The patient always must be in the horizontal position when external cardiac compression is performed since, during cardiac arrest, there is no blood flow to the brain when the body is in the vertical position, even during properly performed external cardiac compression. It is imperative, therefore, to get the cardiac arrest victim into a horizontal position as quickly as possible in situations where he is vertical, such as in a dental chair, trapped in a vehicle, stricken on a telephone pole, while in a stadium seat, or in any similar situation. Elevation of the lower extremities, while keeping the rest of the body horizontal, may promote venous return and augment artificial circulation during external cardiac compression.

Effective external cardiac compression requires sufficient pressure to depress an adult's lower sternum a minimum of 1½ to 2 inches. For external cardiac compression to be effective, the victim must be on a firm surface. This may be the ground, floor, or a spineboard on a wheeled litter. If the victim is in bed, a board, preferably the full width of the bed, should be placed under his back. However, chest compression must not be delayed while this support is awaited.

The rescuer positions himself close to the victim's side and places the long axis of the heel of one hand parallel to and over the long axis of the lower one half of the sternum. Great care must be exercised not to place the hand over the lower tip of the sternum (xiphoid process) that extends downward over the upper abdomen. To avoid this, the rescuer feels the tip of the xiphoid and places the heel of his hand on the lower one half of the sternum about 1 to 1½ inches away from the tip of the xiphoid and toward the victim's head. He then places the other hand on top of the first one (and may interlock the fingers), brings his shoulders directly over the victim's sternum, keeps his arms straight, and exerts pressure almost vertically downward to depress the lower sternum a minimum of 1½ to 2 inches. The compressions must be regular, smooth, and uninterrupted. Relaxation must immediately follow compression and be of equal duration. The heel of the rescuer's hand should not be removed from the chest during relaxation but pressure on the sternum should be completely released so that it returns to its normal resting position between compressions. (See Fig 4.)

Since artificial circulation always must be combined with artificial ventilaton, it is preferable to have two rescuers. One rescuer positions himself at the victim's side and performs external cardiac compression while the other one remains at the victim's head, keeping it tilted back, and continues rescue breathing. *The compression rate for two rescuers is 60 per minute.* When performed without interruption, this rate can maintain adequate blood flow and pressure and will allow cardiac refill. This rate is practical because it avoids fatigue, facilitates timing on the basis of one compression per second, and allows optimum ventilation and circulation to be achieved by quickly interposing one inflation after each five chest compressions without any pause in compressions (5:1 ratio). The rate of 60 compressions per minute allows breaths to be interposed without any pauses. Interposing the breaths without any pauses in compression is important, since any interruption in cardiac compression results in a drop in blood flow and blood pressure to zero. (See Fig 4.)

Two rescuers can perform CPR best when they are on opposite sides of the victim. They can then switch positions when necessary without any significant interruption in the 5:1 rhythm. This is accomplished by the rescuer who is performing artificial ventilation moving to the side of the victim's chest immediately after he has inflated the lungs. He places his hands in the air next to those of the other rescuer who continues to perform external cardiac compression. As soon as the other hands are properly placed, the rescuer performing chest compression removes his hands (usually after the third or fourth in the series of compressions) and the other rescuer then continues

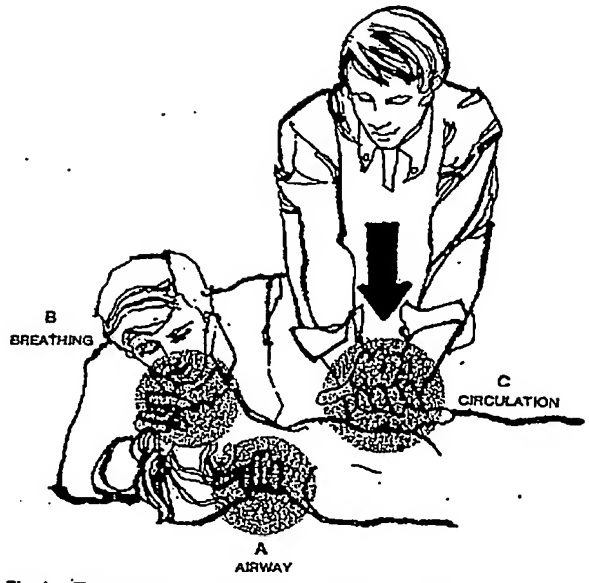


Fig 4.—Two-rescuer cardiopulmonary resuscitation
- 5 chest compressions
  - –Rate of 60/minute
  - –No pause for ventilation
- 1 lung inflation
  - –After each 5 compressions
  - –Interposed between compressions

Fig 5.—One-rescuer cardiopulmonary resuscitation
- 15 chest compressions (rate of 80/minute)
- 2 quick lung inflations

with the series of compressions. The rescuer who had been compressing then moves to the victim's head and interposes the next breath.

If the victim's trachea has been intubated, lung inflation is easier and compression rates up to 80 per minute can be used since breaths can be either interposed or superimposed following endotracheal intubation.

When there is only one rescuer, he must perform both artificial ventilation and artificial circulation using a 15:2 ratio. This consists of *two very quick lung inflations after each 15 chest compressions* (Fig 5). Because of the interruptions for lung inflation, the single rescuer must perform each series of 15 chest compressions at the faster rate of *80 compressions per minute* in order to achieve an actual compression rate of 60 per minute. The two full lung inflations must be delivered in rapid succession, within a period of five to six seconds, without allowing full exhalation between the breaths. If time for full exhalation were allowed, the additional time required would reduce the number of compressions and ventilations that could be achieved in a one-minute period.

Infants and Children.—With a few exceptions, the cardiac compression technique is similar for children. For small children, only the heel of one hand is used, and, for infants, only the tips of the index and middle fingers are used. The ventricles of infants and small children *lie higher in the chest* and the external pressure should be exerted over the midsternum. The danger of lacerating the liver is greater in children because of the pliability of the chest and the higher position of the liver under the lower sternum and xiphoid. Infants require one half to three fourths of an inch compression of the sternum; young children require three fourths to 1½ inches. The compression rate should be 80 to 100 per minute with breaths delivered as quickly as possible after each five compressions.

In infants and small children, backward tilt of the head lifts the back. A firm support beneath the back is therefore required for external cardiac compression and can be provided by the rescuer slipping one hand beneath the child's back while using the other hand to compress the chest. A folded blanket or other adjunct can also be used beneath the shoulders to provide support. For small infants, an alternate method is to encircle the chest with the hands and compress the midsternum with both thumbs.

Checking Effectiveness of CPR.—The reaction of the pupils should be checked periodically during cardiopulmonary resuscitation, since this provides the best indication of delivery of oxygenated blood to the victim's brain. Pupils that constrict when exposed to light indicate adequate oxygenation and blood flow to the brain. If the pupils remain widely dilated and do not react to light, serious brain damage is imminent or has occurred. Dilated but reactive pupils are less ominous. Normal pupillary reactions may be altered in the aged and frequently are altered, in any in-

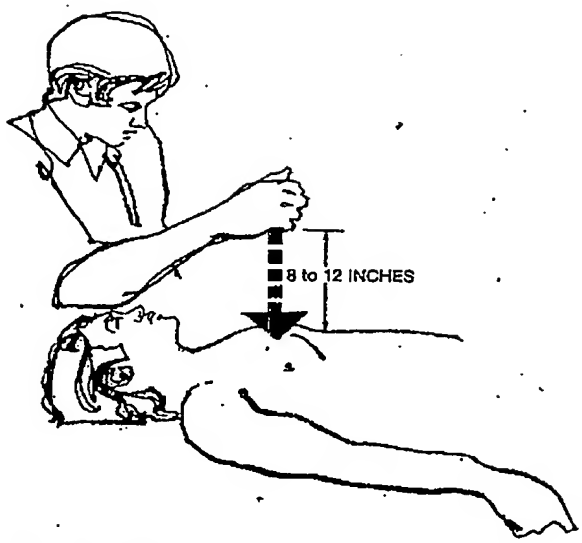


Fig 6.—Precordial thump

dividual, by the administration of drugs.

The carotid pulse should be palpated periodically during CPR in order to check the effectiveness of external cardiac compression or the return of a spontaneous effective heartbeat. This should be done after the first minute of CPR and every few minutes thereafter, when additional rescuers are present and interruptions can be minimized. It should be checked particularly at the time of change of rescuers.

Precordial Thump

Continuing research and clinical experience have delineated a role for the precordial thump, but only in specific types of cardiac arrest cases. Recognizing both its limitations and usefulness, the Conference recommends the precordial thump as a basic maneuver to be used by all levels of rescuers following the detection of pulselessness in adults in these cases:

1. Witnessed cardiac arrest (basic life support)
2. Monitored patient (advanced life support)
3. Pacing known atrioventricular block (advanced life support).

The effectiveness of the precordial thump in the unmonitored patient or in an unwitnessed cardiac arrest has not been determined. Since the myocardium frequently may be anoxic in these situations a specific recommendation for precordial thump cannot be made for them. At this time the precordial thump is not recommended for use on children.

In cases where the primary cause of cardiac arrest is not hypoxia, such as in a witnessed cardiac arrest or in a monitored patient, a single precordial thump may be effective in restarting circulation and may reverse certain dysrhythmias if performed within the first minute after arrest. In those situations, an initial thump on the midsternum using the fist may be the first maneuver performed following the determination of pulselessness.

Such a blow generates a small electrical stimulus in a heart that is reactive. The thump may be effective in restoring a beat in cases of ventricular asystole due to block, and in reversing ventricular tachycardia, or ventricular fibrillation of recent onset. When necessary it may be possible to use the fist as a pacemaker in some cases of heart block. When a series of chest thumps are used for this purpose, the pulse should be palpated before each thump.

The precordial thump is not useful for anoxic asystole and cannot be depended upon to convert an established ventricular fibrillation, nor is it useful for electromechanical dissociation associated with exsanguination. It should not be used for a ventricular tachycardia that is providing adequate circulation.

The precordial thump should be used to provide a stimulus to a potentially reactive heart. However, it is not a substitute for effective external cardiac compression.

There are also hazards associated with the precordial thump. In cases of an anoxic heart that is still beating, the low voltage stimulus may induce ventricular fibrillation. In addition, persons who do not restrict themselves to the recommended single blow may delay starting effective CPR.

In delivering the precordial thump, these rules should be followed:

1. Deliver a sharp, quick single blow over the midportion of the sternum, hitting with the bottom, fleshy portion of the fist struck from 8 to 12 inches over the chest. (See Fig 6.)
2. Deliver the thump within the first minute after cardiac arrest.
3. If there is no immediate response, begin basic life support at once.

The precordial thump is integrated into the basic pattern of CPR differently, depending upon the circumstances surrounding the cardiac arrest. The techniques for using the thump in cases of witnessed arrest or an arrest of a monitored patient are given below.

Technique for Witnessed Cardiac Arrest

1. Tilt the head to open the airway and simultaneously palpate the carotid pulse.
2. If the pulse is absent, give a precordial thump.
3. If the victim is not breathing, give four quick, full lung inflations.
4. If pulse and breathing are not immediately restored, begin one-rescuer or two-rescuer CPR.

Technique for Monitored Patient (For use with patients who have sudden ventricular fibrillation [VF], asystole, or ventricular tachycardia [VT] without pulse.)

1. Give a single precordial thump.
2. Quickly check the monitor for cardiac rhythm and simultaneously check carotid pulse.
3. If there is ventricular fibrillation or ventricular tachycardia without a pulse, countershock as soon as possible.
4. If the pulse is absent, tilt the head, give four quick, full lung inflations.
5. Check the carotid pulse again.
6. If the pulse is absent, begin one-rescuer or two-rescuer CPR.

It must be emphasized strongly that no time should be lost in waiting to assess the results of the precordial thump or by delivering repeated precordial thumps.

Pitfalls in Performance of CPR

When CPR is performed improperly or inadequately, artificial ventilation and artificial circulation may be ineffective in providing basic life support. Enumerated below are important points to remember in performing external cardiac compression and artificial ventilation.

1. Do not interrupt CPR for more than five seconds for any reason, except in the following circumstances.

(*a*) Under emergency conditions, endotracheal intubation usually cannot be accomplished in five seconds. However, it is an advanced life support measure and should be performed only by those who are well trained and well practiced in the technique and *only* after the victim has been properly positioned and all preparations made. Even under these circumstances, interruptions in CPR for endotracheal intubation should never exceed 15 seconds.

(*b*) When moving a victim up or down a stairway, it is difficult to continue effective CPR. Under these circumstances, it is best to perform effective CPR at the head or foot of the stairs, then interrupt CPR at a given signal and move quickly to the next level where effective CPR is resumed. Such interruptions usually should not exceed 15 seconds.

2. Do not move the patient to a more convenient site until he has been stabilized and is ready for transportation or until arrangements have been made for uninterrupted CPR during movement.

3. Never compress the xiphoid process at the tip of the sternum. The xiphoid extends downward over the abdomen. Pressure on it may cause laceration of the liver, which can lead to severe internal bleeding.

4. Between compressions, the heel of the hand must completely release its pressure but should remain in constant contact with the chest wall over the lower one half of the sternum.

5. The rescuer's fingers should not rest on the victim's ribs during compression. Interlocking the fingers of the two hands may help avoid this. Pressure with fingers on the ribs or lateral pressure increases the possibility of rib fractures and costochondral separation.

6. Sudden or jerking movements should be avoided when compressing the chest. The compression should be smooth, regular and uninterrupted (50% of the cycle should be compression and 50% should be relaxation). Quick jabs increase the possibility of injury and produce quick jets of flow; they do not enhance stroke volume or mean flow and pressure.

7. Do not maintain continuous pressure on the abdomen to decompress the stomach while performing external cardiac compression. This may trap the liver and could cause it to rupture.

8. The shoulders of the rescuer should be directly over the victim's sternum. The elbows should be straight. Pressure is applied vertically downward on the lower sternum. This provides a maximally effective thrust, minimal fatigue for the rescuer, and reduced hazard of complications for the victim. When the victim is on the ground or floor, the rescuer can kneel or stand at his side. When he is on a bed or high-wheeled litter, the rescuer must be on a step or chair or kneeling on the bed or litter. With a low-wheeled litter, the rescuer can stand at the victim's side. Problems arise with the use of low-wheeled litters in ambulances. Special arrangements must be made for proper positioning of the rescuer based on the design of the ambulance.

9. The lower sternum of an adult must be depressed 1½ to 2 inches by external cardiac compression. Lesser amounts of compression are ineffectual since even properly performed cardiac compression provides only about one quarter to one third of the normal blood flow.

10. While complications may result from improperly performed external cardiac compression and precordial thumps, even properly performed external cardiac compression may cause rib fractures in some patients. Other complications that may occur with properly performed CPR include fracture of the sternum, costochondral separation, pneumothorax, hemothorax, lung contusions, lacerations of the liver, and fat emboli. These complications can be minimized by careful attention to details of performance. It must be remembered, however, that during cardiac arrest, effective cardiopulmonary resuscitation is required even if it results in complications, since the alternative to effective CPR is death.

Special Resuscitation Situations

Drowning.—Extensive research has delineated the events and mechanisms of drowning and the detailed physiological variations between fresh water and sea water submersion. However, basic life support resuscitation procedures following drowning are the same as basic life support principles presented above, and CPR should be performed as quickly as possible. There are a few special considerations, given below:

1. When attempting to rescue a drowning victim, the rescuer should get to him as quickly as possible, preferably with some conveyance, such as a boat or surfboard. If a conveyance is not available, a flotation

device should be carried by the rescuer. The rescuer always must exercise care not to endanger himself while trying to aid a drowning person.

2. External cardiac compression should never be attempted in the water because it is impossible to perform it there effectively.

3. Mouth-to-mouth or mouth-to-nose ventilation may be performed in the water, although it is difficult and often impossible in deep water unless the rescuer has some type of flotation device to support the victim's head.

4. Artificial ventilation always should be started as soon as possible, even before the victim is moved out of the water, into a boat or onto a surfboard. As soon as the rescuer can stand in shallow water he should begin artificial ventilation.

5. In cases of suspected neck injury, the victim must be floated onto a back support before being removed from the water. If artificial respiration is required, the routine head tilt or jaw thrust maneuvers should not be used. Artificial ventilation should be accomplished with the head maintained in a neutral position and using a modified jaw thrust maneuver (as described under "Accident Cases," p 843).

6. When removed from the water, the victim should have standard artificial ventilation or cardiopulmonary resuscitation performed according to the standards previously described.

7. Drowning victims swallow large volumes of water and their stomachs usually become distended. This impairs ventilation and circulation and should be alleviated as soon as possible. To relieve the distension, the victim may be turned on his side and his upper abdomen compressed or he may be turned over quickly into the prone position and lifted with the rescuer's hands under the stomach to force water out. This is referred to as "breaking" the victim.

8. There should be no delay in moving the victim to a life support unit where advanced life support capabilities are available. Every submersion victim, even one who requires only minimal resuscitation, should be transferred to a medical facility for follow-up care.

Electric Shock.—Electric shock may induce a variety of phenomena ranging from the benign to the lethal. The outcome depends largely upon the amplitude and duration of contact with the current. Other than burns of varying severity and injuries due to falls, the possible emergency events to be recognized include:

1. Tetany of the musculature of breathing, which is usually confined to the duration of the shock but may produce secondary cardiac arrest if the tetanizing shock is of a prolonged duration.

2. Prolonged paralysis of respiration, which may result from a massive convulsive phenomenon and may last for minutes after the shock current has terminated.

3. Ventricular fibrillation or other serious cardiac arrhythmias (such as runs of premature ventricular contractions or ventricular tachycardia that may progress to ventricular fibrillation) produced by low voltage currents (110 to 220 v) sustained for several seconds.

The prognosis for victims of electric shocks is not predictable easily since the amplitude and duration of the charge usually are not known. Failure of either respiration or circulation is likely to result.

After safely clearing a victim from an energized object, the rescuer should determine his cardiopulmonary status immediately. If spontaneous respiration or circulation is absent, the technique of cardiopulmonary resuscitation outlined in this statement should be initiated.

In cases where electric shock occurs on a public utility pole, a precordial thump should be delivered and mouth-to-mouth ventilation started at once. The victim must *then* be lowered to the ground as quickly as possible. CPR is only effective when performed on a victim in the horizontal position.

Beginning and Terminating Basic Life Support

CPR is most effective when started immediately after cardiac arrest. If cardiac arrest has persisted for more than ten minutes, cardiopulmonary resuscitation is unlikely to restore the victim to his pre-arrest central nervous system status. If there is any question of the exact duration of the arrest, the victim should be given the benefit of the doubt and resuscitation started.

Basic life support is not indicated for a victim who is known to be in the terminal stages of an incurable condition. When resuscitation is indicated and started in the absence of a physician, it should be continued until one of the following occurs:

1. Effective spontaneous circulation and ventilation have been restored.

2. Resuscitation efforts have been transferred to another responsible person who continues basic life support.

3. A physician assumes responsibility.

4. The victim is transferred to properly trained and designated professional medical or allied health personnel charged with responsibilities for emergency medical services.

5. The rescuer is exhausted and unable to continue resuscitation.

The decision to stop resuscitative efforts is a medical one. (See sections on "Advanced Life Support" and "Medicolegal Considerations.")

Training and Certification in Basic Life Support

Artificial Ventilation Only.—Every effort should be made to teach artificial ventilation to all members of the general public. Training the entire population should be accomplished through American National Red Cross courses, as well as through schools, YMCA's, clubs, local groups, and medical, paramedical and rescue organizations. All school children should be required to have annual training in artificial ventilation beginning

in the fifth grade, and a major national effort should be mounted to achieve this objective in the shortest possible time..

The Conference further recommends that training should be provided by courses conducted by trained and certified instructors according to the technique described above and in accordance with the training standards of the American Heart Association. For optimum results, training should include such media as lectures, demonstrations, posters, slides, and movies. Actual practice on training manikins is required to assure efficiency of performance. Acceptable manikins must simulate obstruction of the airway when the head is not tilted back maximally, allow mouth-to-mouth and mouth-to-nose ventilation, and simulate rise of the chest when the lungs are inflated. Training should be to a level of demonstrated proficiency in mouth-to-mouth and mouth-to-nose resuscitation on adult manikins and mouth-to-mouth-and-nose resuscitation on infant manikins.

Basic Life Support.—CPR is an emergency procedure that requires special training both to recognize cardiopulmonary arrest and to perform artificial ventilation and artificial circulation. In order to ensure the widest possible benefits of its application, programs should be started to train the general public in basic life support according to the recommended American Heart Association standards. Initially, groups with the greatest need such as policemen, firemen, rescue workers, lifeguards, high-risk industry workers, and families of cardiac patients may receive preference, but the goal should be to train the general public, starting with school children at the eighth grade level.

Basic life support training of the public should be under the auspices of the American National Red Cross, the YMCA, and comparable volunteer and public service agencies concerned with saving lives. Training programs must adhere to the standards of the American Heart Association. These agencies should participate in training CPR instructors to teach basic life support and in certifying allied health personnel and nonmedical groups, public specialty groups, school children, and other segments of the population according to the training and performance standards of the American Heart Association as recommended by the National Research Council.

In addition to lectures, demonstrations, and films, actual practice and demonstration of proficiency in both the ventilatory and the circulatory components of cardiopulmonary resuscitation are required on training manikins. CPR cannot be taught or practiced on conscious or unconscious human subjects.

Manikins used in CPR training programs must provide (*a*) airway obstruction when the neck is flexed, (*b*) effective chest movement as a result of proper lung ventilation via mouth or nose, and (*c*) adequate movement of the sternum as a result of properly applied external cardiac compression against resistance. In addition, it is desirable for training devices to provide a simulated carotid pulse and an objective means (lights, gauges, strip chart) by which the student or instructor can determine adequacy of lung inflation and chest compression and mistakes in hand position. Palpation of the actual carotid pulse should also be practiced on other trainees.

To simplify instruction in basic life support, initial training should cover the recommended A-B-C sequence used for an unwitnessed cardiac arrest. When the trainee understands and can perform this effectively, further instruction should include use of precordial thump for witnessed cardiac arrest and for monitored patients.

Certification in CPR.—The purpose of certification is, as far as possible, to maintain adherence to uniform national standards established or recognized by the American Heart Association. Certification will be accomplished through the use of national cognitive (written or oral) and performance examinations. Receipt of certification will be contingent on satisfactory completion of such examinations and will indicate that the person certified was found to be qualified at the time of examination to perform and/or teach those, and only those, emergency techniques indicated by the certifying individual or agency. The process of training, certification, and recertification is intended to develop and maintain a mechanism for emergency cardiac care and resuscitation that is both broadly available and uniformly effective, in a manner most consistent with the public interest and safety. Certification does not imply that the American Heart Association or any designated certifying individual or agency either warrants or assumes responsibility for the performance of individuals subsequent to their certification.

An initial course leading to certification in CPR should be for small groups and should include didactic presentations and sufficient supervised, intensive manikin practice for every student to become proficient in detecting breathlessness and pulselessness and in performing the sequential steps of rescue breathing and external cardiac compression. Both one-rescuer and two-rescuer CPR should be practiced.

Periodic recertification or refresher courses that include retesting on manikins are required for all personnel, including instructors. The exact frequency for such recertification may need to be regulated on the basis of the professional skill and experience of particular groups. At present, suggested requirements for nonmedical groups are recertification one year from the initial course and then at least every three years thereafter, or more frequently where indicated.

CPR Instructors.—CPR instructors should be highly motivated individuals who represent special or organized groups in the community in which they will provide CPR training, have a background in or the capability for teaching, have an interest in or a role in the delivery of CPR, have completed an initial CPR course, and have successfully completed the CPR instructor's course according to American Heart Association standards and have a valid instructor's cer-

tificate.

Certification of instructors will indicate that the recipient has passed the examination for instructor certification as defined elsewhere in this statement, and it will authorize the holder to conduct CPR courses according to standards of the American Heart Association. Certification of instructors is not intended to imply that the American Heart Association or any other certifying agency warrants or assumes responsibility for the performance of individuals trained by such certified instructors.

Certification of instructors is valid for a specified time and must be renewed periodically. If instructors are actively engaged in CPR instruction or performance and are familiar with new techniques, they may be recertified after review by local certifying authorities. If they are not actively engaged in training, they should attend a recertification course as detailed above.

Conference Recommendations.—The Conference recommends that CPR training be given to all eighth grade pupils and that it be repeated each year through high school. Additional pilot studies are required to determine the effectiveness of newer training methods.

The Conference mandates that CPR courses be required as part of the curriculum of all medical, dental, nursing, osteopathic, respiratory therapy, and other allied health schools. In order to implement this, the Association of American Medical Colleges should be made aware of this requirement so that all schools include instruction in basic life support and require a demonstration of proficiency in performance of this technique as part of their curricula.

The Conference recommends that every hospital with acute care facilities must assign to a specific committee the responsibilities for providing CPR teams on a 24-hour-per-day basis and that they be capable of performing CPR and all aspects of emergency life support. The CPR or emergency life support team should consist of nurses, technicians, respiratory therapists, house staff, and on-call attending staff. Wherever possible, the CPR hospital committee should be composed of, at least, a surgeon, a cardiologist, an anesthesiologist, an in-service nurse, and an administrator. The committee should be responsible for providing a written plan of action (protocol), CPR training and practice sessions, and a record of CPR occurrences available for periodic audit and review.

The Conference recommends that all nurses and physicians, including house staff, should be competent in all phases of CPR. To accomplish this, it is recommended that all hospitals require that, for annual staff reappointment, all physicians must either:

1. Demonstrate proficiency in basic life support through participation in actual resuscitation efforts or in teaching CPR to others, or
2. Agree to attend an approved training or retraining course offered by the hospital or their local heart association.

All hospital medical and nursing emergency department personnel must be trained and certified in basic and advanced life support, and all allied health personnel must be trained in basic life support.

The Conference further recommends that all hospitals and all state boards of health, divisions of hospital licensing, change their rules to conform to the above requirements and that they be included in the standards for hospital accreditation by the Joint Commission on Accreditation of Hospitals and as a stated policy of the American Hospital Association.

Part III.—Advanced Life Support

As used in this statement, advanced life support consists of the following elements:

1. Basic life support.
2. Using adjunctive equipment and special techniques, such as endotracheal intubation and open chest internal cardiac compression.
3. Cardiac monitoring for dysrhythmia recognition and control.
4. Defibrillating.
5. Establishing and maintaining an intravenous infusion lifeline.
6. Employing definitive therapy, including drug administration (*a*) to correct acidosis and (*b*) to aid in establishing and maintaining an effective cardiac rhythm and circulation.
7. Stabilization of the patient's condition.

In some cases, advanced life support includes transportation that has (*a*) communication to ensure continuity of care and (*b*) the capability of constant monitoring and life support until the patient has been transported and admitted to a continuing care facility.

Advanced life support may be provided either by nonmobile life support units or by mobile life support units. Each unit must be staffed with highly trained personnel and specialized equipment in order to deliver the quality of care demanded by the criteria listed above. Each of these elements of advanced life support includes various components as described below.

Basic Life Support

All approaches to advanced life support must include a well-established basic life support capability, as described in Part II, "Basic Life Support," and illustrated in the frontispiece and in Fig 1, Life Support Decision Tree.

Adjunctive Equipment and Special Techniques

Adjunctive equipment is not essential for cardiopulmonary resuscitation. It may be used when it becomes available, but only by specialized personnel who have had adequate training with the specific devices to be used. Basic life support should not be delayed while awaiting equipment, nor should use of equipment result in diverting attention or effort from basic resuscitative measures. When considering adjunctive equipment, it must be remembered that personnel must be trained to a level of demonstrated proficiency in the use of adjunctive equipment, even equipment of a relatively simple nature. In addition, adjunctive equipment must be tested periodically for satisfactory performance according to prescribed regulations. Adequate records of such tests also must be maintained.

Adjuncts for Airway and Ventilation

Oxygen.—Supplemental oxygen should be used as soon as it becomes available. Rescue breathing (exhaled air ventilation) will deliver about 16% to 17% oxygen to the patient. Ideally, this will produce an alveolar oxygen tension of 80 torr. However, because of the low cardiac output (large arteriovenous O_2 gradient) associated with external cardiac compression and the presence of intrapulmonary shunting and ventilation-perfusion abnormalities, marked discrepancies will occur between the alveolar and arterial oxygen tension and hypoxemia may ensue. Hypoxemia leads to anaerobic metabolism and metabolic acidosis, which frequently impair the beneficial effects of chemical and electrical therapy.

Because of this, the Conference recommends that supplemental oxygen always be used when bag-valve-mask or bag-valve-tube systems are used. This will enhance myocardial and cerebral oxygenation that is essential for successful resuscitation.

Oropharyngeal Airway.—Oropharyngeal airways should be used whenever a bag-valve-mask system or automatic breathing device with mask is used, but only if done by an individual properly trained in their use. Airways should be used only on deeply unconscious persons. If introduced into a conscious or stuporous person, they may promote vomiting or laryngospasm. Care is required in the placement of the airway because incorrect insertion can displace the tongue back into the pharynx and produce airway obstruction. Oropharyngeal airways should be available in infant, child, and adult sizes. Nasopharyngeal airways also may be used for adults. As with all adjunctive equipment, explicit training and practice is required for their use.

S-Tube.—Numerous S-tube airway adjuncts are available. They range from simple tubes with mouthpieces and bite blocks to more elaborate devices with valves. Despite many different designs, they share certain limitations.

S-tubes

1. Do not provide as effective an airway seal as direct mouth-to-mouth or mouth-to-mask ventilation.

2. Do not reduce potential transmission of infection.
3. Require training for safe and effective use.
4. Induce vomiting if used improperly.
5. Require the single rescuer to move to the victim's head and reposition the S-tube to inflate the lungs between chest compressions.

S-tubes do offer useful features, such as

1. Overcoming aesthetic problems of direct mouth-to-mouth contact.
2. Assisting in maintaining a patent airway.
3. Keeping the mouth open.

However, it is generally found that direct mouth-to-mouth or mouth-to-mask ventilation provide more effective artificial ventilation.

Masks.—Well-fitting masks have proven to be an effective, simple adjunct available for use in artificial ventilation by medical, allied health, and nonmedical personnel. Manikin practice with masks should be required for all personnel who are likely to use a mask for mouth-to-mask ventilation. The mask may be a standard anesthesia mask or a folding pocket mask and should have the following characteristics: transparent material, well-sealing cuff, headstraps, oxygen insufflation inlet, 15 mm/22 mm coupling size, and availability in one average size for adults and additional sizes for infants and children. The mask is most effectively used when the rescuer positions himself at the top of the patient's head and uses the jaw thrust maneuver, as described on page 841.

Bellows Devices.—Bellows devices are *ineffectual* for providing artificial ventilation. The Conference condemns all ventilation bellows that have been made commercially available. All of them suffer a common design flaw so that even professional rescuers cannot provide adequate lung ventilation when applying downward or sideward compression with a bellows. *Bellows devices should not be used for resuscitation.*

Bag-Valve-Mask Devices.—When bag-valve-mask units are used, they usually provide less ventilatory volume than mouth-to-mouth or mouth-to-mask ventilation because of the difficulty in providing a leakproof seal to the face while maintaining an open airway. For this reason, the manually-operated, self-inflating bag-valve-mask units can be used effectively only by well-trained and experienced medical personnel, such as anesthesiologists.

Extensive specialized training and demonstrated continuing proficiency is required with the bag-valve-mask device. The rescuer must position himself at the top of the victim's head. He then must maintain the head in extension, keep the lower jaw elevated, and secure an optimum mask fit with one hand while using the other hand to squeeze the bag. Attempts have been made to achieve effective ventilation with these devices by using two rescuers, one to hold the mask and one to squeeze the bag, but this is an awkward procedure.

Because of this difficulty in using the bag-valve-mask unit, the Conference recommends that these devices be used only when the patient has a cuffed endotracheal tube or a cuffed esophageal obturator airway inserted. Either of these tubes will ensure delivery of an adequate volume of oxygen-enriched atmosphere and will prevent gastric insufflation and aspiration of stomach contents. When an endotracheal tube or esophageal obturator airway is used the rescuer may position himself at the victim's side. When a mask is used, the rescuer always should position himself at the top of the victim's head and not at his side.

An adequate bag-valve-mask unit should fulfill these criteria:

1. Self-refilling, *but without sponge rubber inside*—because of difficulty in cleaning, disinfecting, eliminating ethylene oxide, and fragmentation.
2. Non-jam valve system at 15 liters/minute oxygen inlet flow.
3. Transparent, plastic face mask with an air-filled or contoured, resilient cuff.
4. No pop-off valve, except pediatric models.
5. Standard 15 mm/22 mm fittings.
6. System for delivery of high concentrations of oxygen through an ancillary oxygen inlet at the back of the bag or via an oxygen reservoir.
7. True nonbreathing valve.
8. Oropharyngeal airway.
9. Satisfactory for practice on manikins.
10. Satisfactory performance under all common environmental conditions and extremes of temperature.
11. Available in adult and pediatric sizes.

Esophageal Obturator Airway.—The esophageal obturator airway is a recent innovation in the management of cardiac arrest patients. It appears to be a useful airway adjunct, but its future role remains to be determined. The airway consists of a cuffed endotracheal tube mounted through a face mask and modified with a soft plastic obturator blocking the distal orifice and multiple openings in the upper one third of the tube at the level of the pharynx. It is passed into the esophagus. The mask then is seated on the face and the cuff inflated. When mouth-to-tube or bag-valve-tube ventilation is performed, the air is discharged through the pharyngeal openings in the tube and passes down the trachea since the esophagus is blocked. This prevents gastric distension and regurgitation during resuscitation. The esophageal obturator airway should only be inserted in patients who are not breathing or who are deeply unconscious.

The potential advantages of the esophageal obturator airway are that no visualization is required for introduction and that it can be introduced more easily and quickly than an endotracheal tube. In a large series of cardiac arrest cases, the airway has been shown to be used successfully without injury to the esophagus when used by professional allied health personnel who had been trained in its use on intubation manikins and unconscious patients.[41] However, the potential for damage to the esophagus is ever present unless use of the airway is restricted to adequately trained individuals.

Removal of the esophageal airway frequently is followed by immediate regurgitation. In order to cope with this, the airway should not be removed until the patient is conscious and breathing or has a return of reflexes. When it is to be removed, the patient should be turned on his side and adequate suction should be available. It is also possible to pass a nasogastric tube around the esophageal tube and decompress the stomach prior to removing the esophageal tube. A standard cuffed endotracheal tube can be introduced into the trachea prior to removal of the esophageal tube.

Endotracheal Intubation.—Oxygenation of the lungs by exhaled-air methods or by simple airway adjuncts should always precede attempts at tracheal intubation. Adequate lung inflations interposed between external cardiac compressions require high pharyngeal pressures. These pressures promote gastric distension, which elevates the diaphragm and interferes with adequate lung inflation. This distension promotes regurgitation, with the potential hazard of aspiration of gastric contents into the lungs. Therefore, the trachea should be intubated as soon as practical by trained personnel. This isolates the airway, keeps it patent, prevents aspiration, and assures the delivery of a high concentration of oxygen to the lungs. With a cuffed endotracheal tube (or esophageal obturator airway), it is easier to provide adequate ventilation since it is not necessary to interpose breaths as with direct mouth-to-mouth, mouth-to-mask, or bag-valve-mask techniques. It then becomes possible to use a faster, uninterrupted chest compression rate of 80 per minute and provide better artificial circulation.

Because of the difficulties, delays, and complications in properly placing an endotracheal tube, its use should be restricted to medical personnel and professional allied health personnel who are highly trained and either use endotracheal intubation frequently or are retrained frequently in this technique.

The indications for endotracheal intubation include:

1. Cardiac arrest
2. Respiratory arrest
3. Inability of rescuer to ventilate the unconscious patient with conventional methods
4. Inability of the patient to protect his own airway (coma, areflexia), or
5. Prolonged artificial ventilation.

The Conference recommends that all emergency department training programs and equivalent programs give satisfactory training to all professional personnel in the safe and effective introduction of endotracheal tubes.

Endotracheal tubes should be available in various sizes. They should have standard 15 mm/22 mm fittings, be provided with a stylet, be cuffed for adults and older children, and be uncuffed for infants and small children. The recommended sizes for endotracheal tubes are given in Table 1.

Table 1.—Recommended Sizes for Endotracheal Tubes and Suction Catheters*

Age	Endotracheal Tube (Internal Diameter)	Suction Catheters
Newborn	3.0 mm	6 Fr.
6 months	3.5 mm	8 Fr.
18 months	4.0 mm	8 Fr.
3 years	4.5 mm	8 Fr.
5 years	5.0 mm	10 Fr.
6 years	5.5 mm	10 Fr.
8 years	6.0 mm	10 Fr.
12 years	6.5 mm	10 Fr.
16 years	7.0 mm	10 Fr.
Adult (Female)	8.0-8.5 mm	12 Fr.
Adult (Male)	8.5-9.0 mm	14 Fr.

*One size larger and one size smaller should be allowed for individual variations.

Oxygen-Powered Mechanical Breathing Devices:

CONVENTIONAL PRESSURE-CYCLED AUTOMATIC RESUSCITATORS (IPPB respirators, positive-negative pressure resuscitators, resuscitators-inhalators) should not be used in conjunction with external cardiac compression because effective external cardiac compression prematurely triggers termination of the inflation cycle so inadequate ventilation results. These devices are complex, difficult to use, more costly, and relatively less effective, even for artificial ventilation alone, than oxygen-powered ventilation devices that are manually triggered (time-cycled).

MANUALLY TRIGGERED (TIME-CYCLED) DEVICES are easier to use effectively. They have high instantaneous flow rates that allow them to be used for artificial ventilation alone. The devices also allow breaths to be interposed between compressions during CPR. Most will function as inhalators too, for patients who are breathing spontaneously but require oxygen.

Manually triggered, oxygen-powered resuscitators should be able to

1. Provide instantaneous flow rates of 100 liters/minute or more and an inspiratory pressure safety release valve that opens at 50 cm of water, although it is recognized that this high instantaneous flow rate usually will result in gastric distension unless a cuffed endotracheal tube or cuffed esophageal obturator airway is used.
2. Provide 100% oxygen.
3. Operate satisfactorily under environmental conditions, including all temperature extremes found in North America.

They also should have the following minimum design criteria:

1. A standard 15 mm/22 mm coupling for mask, endotracheal tube, esophageal airway, and tracheostomy tubes.
2. A rugged, breakage-resistant mechanical design that is compact and easy to hold.
3. A trigger positioned so that both hands of the rescuer can remain on the mask to hold it in position while supporting and tilting the head and keeping the jaw elevated.

Suction Devices.—Portable and installed suction equipment should be available for resuscitation emergencies. The portable unit should provide vacuum and flow adequate for pharyngeal suction. It should be fitted with large-bore, non-kinking suction tubing and semirigid pharyngeal suction tips. There should be multiple sterile suction catheters of various sizes for suctioning via endotracheal or tracheostomy tubes, a nonbreakable collection bottle, and a supply of water for rinsing tubes and catheters.

The installed suction unit should be powerful enough to provide an air-flow of over 30 liters/minute at the end of the delivery tube and a vacuum of over 300 mm Hg when the tube is clamped. The amount of suction should be controllable for use on children and intubated patients.

There should be an additional set of rigid pharyngeal suction tips (tonsil suction tips) and sterile curved tracheal suction catheters of various sizes. For tracheal suction, a Y- or T-piece, or a lateral opening, should be between the suction tube and suction source for on-off control. The suction yoke, collection bottle, water for rinsing, and suction tube should be readily accessible to the attendant at the head of the litter. The tube should reach the airway of any patient, regardless of his position. Suction apparatus must be designed for easy cleaning and decontamination.

Nasogastric Tube for Gastric Decompression.— It is preferable to insert a nasogastric tube after the airway has been isolated by endotracheal intubation. However, if gastric distension interferes with adequate ventilation, a nasogastric tube may be inserted at an earlier time by trained medical, nursing, or authorized allied health personnel. External cardiac compression should not be interrupted during this procedure.

Adjuncts for Artificial Circulation

Bedboard.—Cardiopulmonary resuscitation should be performed at the site where the victim was found, whether inside or outside the hospital. If the cardiac arrest occurs in a hospital bed, a firm support should be provided beneath the patient's back when CPR is performed. A simple serving tray or support of comparable size is useful but not best. To provide proper support, a bedboard that extends from the shoulders to the waist and across the full width of the bed should be available. Spineboards should be used for ambulance services and mobile life support units. Spineboards also are useful for extricating and immobilizing victims. They may be used directly on the floor of the emergency vehicle or on a wheeled litter.

Manual Chest Compressors.—Simple, hinged, manually operated mechanical chest compressors can be used for effective external cardiac compression. They should provide an adjustable stroke of 1½ to 2 inches and be able to be applied with interruptions in manual CPR of no longer than five seconds each. These compressors are inexpensive and make it easier for an individual to provide prolonged, effective external cardiac compression.

Automatic Chest Compressors.—Optimum management of persons with cardiac arrest is obtained when the definitive therapy required to restore spontaneous circulation and to stabilize the victim is available at the site of the arrest, prior to any transportation that may be necessary. When this is not possible, the use of an automatic mechanical device provides the most consistently effective cardiopulmonary resuscitation during transportation or prolonged resuscitation. When such devices are used, external cardiac compression always must be started with the manual method first. Physicians and other medical personnel who will be using the automatic equipment must have careful and extensive training and manikin practice in the manual method, the mechanical method, and the proper technique for changing from one to the other without interrupting CPR for more than 5 to 10 seconds at any one time. A well-trained and coordinated team of persons is necessary to use the compressor.

These devices eliminate the operator fatigue that causes variations in cardiac output, and they provide simultaneous ventilation with high oxygen concentrations. While these devices afford more regular and uninterrupted CPR, they have the following limitations:

1. They are relatively heavy and difficult to move because of their associated oxygen tanks and components.
2. They may be difficult to use without accidentally displacing the plunger while moving a victim up and down stairs or on a steep incline.
3. The use of commercially available models is limited to adults.

Compressor-ventilators should be employed only with a cuffed endotracheal tube, esophageal airway, or, if used with a mask, only by well-trained and experienced personnel. Their performances should be comparable to that recommended for the manual method.

Internal Cardiac Compression

Internal cardiac compression is indicated in certain conditions where external cardiac compression may be ineffective. These circumstances include penetrating wounds of the heart and other internal thoracic injuries, cardiac tamponade, tension pneumothorax with mediastinal displacement, chest or spinal deformities, and severe emphysema causing barrel-type chest. If it is suspected or can be determined that any of these conditions is present, or, if closed chest cardiac compression does not appear to establish sufficiently effective artificial circulation, open chest internal cardiac compression may be performed in conjunction with artificial ventilation.

Open chest cardiac compression should only be performed by a physician with the necessary skill, equipment, and facilities. In this procedure, a thoracotomy is performed through the left fifth intercostal space and the pericardial sac is opened to allow direct manual cardiac compression.

Cases of crushed chest or flail chest may require

only effective artificial ventilation. If there is cardiac arrest so that artificial circulation also is required outside of a hospital, external cardiac compression may be used with the recognition that, while it may compound internal injuries, it represents the only alternative to certain death.

If a tension pneumothorax is suspected in an emergency situation, a large bore needle may be inserted on the side of the pneumothorax through the second intercostal space 2 inches from the midline. If the diagnosis is confirmed, this should be replaced with a chest tube and valve or an underwater seal drainage as soon as possible.

In trauma cases, especially chest trauma, it may be very difficult to detect evidence of circulatory activity. Special efforts, including palpation of femoral and carotid pulses and auscultation for heart sounds, may be required to determine the cardiac status. Individuals who deal frequently with serious trauma cases should be trained thoroughly in CPR and its possible complications.

Cardiac Monitoring

Electrocardiographic (ECG) monitoring should be established immediately on all patients who present symptoms of suspected heart attack or sudden collapse.

Most sudden deaths following acute myocardial infarction are due to electrical derangement of the rhythm of the heart (dysrhythmias). Susceptibility to electrical derangement is greatest immediately following and several hours after myocardial damage or severe ischemia. It is during this critical and unstable period that patients should be under continuous and critical monitoring.

Although rhythm changes may occur abruptly and without warning, potentially lethal situations usually can be prevented by early detection and prompt treatment.

Each person providing advanced life support must have adequate training and testing to establish his capability of dysrhythmia detection and treatment. Once trained, his competency must be reenforced and examined continually. This can be accomplished through regularly scheduled assignment to hospital patient care, such as in the emergency department, coronary care unit, intensive care unit, or operating room.

ECG monitoring is a vital step in the prevention of cardiac arrest in patients with acute myocardial infarction. Personnel providing advanced life support must be familiar with monitoring equipment, including its problems and artifacts. They also must be capable of recognizing, at a minimum, the following electrocardiographic dysrhythmias:

1. Cardiac standstill (ventricular asystole).
2. Bradycardia (rate of less than 60 per minute).
3. The difference between supraventricular and ventricular rhythms.
4. Premature ventricular contractions (frequency, multifocal, and R on T).
5. Ventricular tachycardia.
6. Ventricular fibrillation.
7. Atrioventricular blocks of all degrees.
8. Atrial fibrillation and flutter.

In addition to recognizing these dysrhythmias, all personnel must be familiar with the potential dangers inherent in each waveform and with the therapeutic regimen that is required when any one of them is present.

In situations in which the initial emergency problem is a cardiac arrest, CPR steps and techniques outlined under "Basic Life Support" should be initiated. As quickly as possible thereafter, ECG electrodes should be applied. For this purpose, a monitor-defibrillator with combination ECG electrode-defibrillator paddles is recommended. These ECG electrode-defibrillator paddles are applied to the chest and an immediate determination of the cardiac rhythm may be made.

If ventricular fibrillation is present, defibrillation should be immediate. (See section on "Defibrillation.")

If there is a relatively regular ECG rhythm, pulse and blood pressure should be checked immediately to determine if electromechanical dissociation is present.

If the rhythm and circulation are satisfactory, oxygen should be administered, an intravenous lifeline established, and regular ECG electrodes applied for continuous monitoring.

Drugs, as indicated in the section on "Drugs and Definitive Therapy," should be used to maintain a stable cardiac rhythm and adequate circulation.

Monitoring and supportive therapy should be continued in situations where communications must be established to transfer the patient.

Defibrillation

Defibrillation produces a simultaneous depolarization of all muscle fascicles of the heart, after which a spontaneous beat may resume if the myocardium is oxygenated and not acidotic. Direct current defibrillator shocks should be delivered as soon as possible when the heart is known to be in ventricular fibrillation. Countershocks also are indicated on an emergency basis in the presence of ventricular tachycardia without a peripheral pulse. It has not been demonstrated that defibrillation is useful in cases of ventricular asystole, although it is sometimes used when it is impossible to be sure whether the heart is in a fine ventricular fibrillation or true ventricular standstill.

For defibrillation, the standard electrode position always should be used: one electrode just to the right of the upper sternum below the clavicle and the other electrode just to the left of the cardiac apex or left nipple. Standard electrode paste may be used but saline-soaked four by four gauze sponges are also excellent conductors. The sponges may be applied rapidly and external cardiac compression may be resumed after defibrillation without the problem of hand slippage on the chest that occurs when electrode paste is used.

A single defibrillator shock does not produce serious functional damage to the myocardium; so there is no

reason to withhold it in the unconscious, pulseless adult patient when a direct current defibrillator is available even though the patient is unmonitored. In these circumstances, unmonitored defibrillation with a single shock may be performed by medical or properly trained and authorized allied medical personnel. It must be emphasized that this single shock must not delay the prompt application of basic life support measures in any way. *Unmonitored defibrillation is not recommended for children.*

In instances of apparent cardiac arrest secondary to hypoxemia, eg, drug overdose, CPR for a period of two minutes is recommended, with reevaluation prior to the delivery of an unmonitored defibrillator shock.

The optimum amount of electrical energy has not been established and there are no conclusive data concerning the ideal defibrillator output waveform. The output delivered into a 50-ohm load should range from 0 to at least 250 watt-seconds, preferably 300 watt-seconds for the conventional Lown waveform.[22] This range will provide adequate energy for the majority of patients. The energy requirements of defibrillators with other waveforms may vary from this range. In emergency situations, it has been customary to deliver a maximum shock of 400 joules (watt-seconds) for cases of ventricular fibrillation. However, lower settings frequently are effective in converting ventricular fibrillation and ventricular tachycardia and produce less myocardial damage. The damage resulting from defibrillator shocks is directly proportional to the energy used, and maximal settings, when not required, may further impair an already damaged myocardium. The energy level delivered through a 50-ohm load should be indicated on the front panel of the defibrillator. All defibrillators, particularly those that register stored energy, should be checked at regular, frequent intervals with suitable test equipment to determine the delivered energy. Breakdown and defects develop in units that are used frequently at high energy levels. Well-organized, detailed, and recorded preventive maintenance should be performed regularly also.

Establishing and Maintaining Intravenous Infusion

It is essential to provide an intravenous route for the intermittent or continuous rapid administration of drugs and fluids that may be required to reestablish or support a stable cardiac rhythm and adequate circulation. This route must be established as early as possible and must be a routine part of advanced life support.

Drugs and Definitive Therapy

Drug administration and other forms of definitive therapy are required for most patients who receive cardiopulmonary resuscitation or emergency cardiac care. Tracheal intubation by trained personnel and the early administration of high concentrations of oxygen are of major importance in reducing hypoxemia during the cardiorespiratory emergency. While the dangers of hypoxemia are easily demonstrated experimentally and clinically, there is no evidence that lung damage occurs with high concentrations of oxygen if it is used for periods of less than 24 hours.

Drug administration is of critical importance in emergency cardiac care. Drugs usually are administered intravenously during the cardiopulmonary resuscitation emergency to ensure their delivery into the cardiovascular system as artificial circulation is provided. A cutdown or long-term intravenous route should be established as early as possible. Intracardiac injections are sometimes used, but this route is usually limited to epinephrine early in the cardiac arrest and before an intravenous infusion has become available.

For purposes of these Conference recommendations, drugs are divided into two categories: essential and useful.

Essential Drugs
- Sodium bicarbonate
- Epinephrine
- Atropine sulfate
- Lidocaine
- Morphine sulfate
- Calcium chloride

(Oxygen is also considered an essential drug.)

Sodium Bicarbonate.—Sodium bicarbonate is necessary to combat metabolic acidosis. It is administered intravenously in an initial dose of 1 mEq/kg by either bolus injection or continuous infusion over a ten-minute period. Once effective spontaneous circulation is restored, further administration of sodium bicarbonate usually is not indicated and may be harmful.

The available dosage forms for sodium bicarbonate are:

1. Prefilled syringe: 50 ml of 8.4% sol. (50 mEq)
   50 ml of 7.5% sol. (44.6 mEq)
2. Ampules: 50 ml of 8.4% solution (50 mEq)
   50 ml of 7.5% solution (44.6 mEq)
3. Bottles: 500 ml of 5% solution (297.5 mEq)

The dosage of 1 mEq/kg should be used regardless of dosage form.

Where ventricular fibrillation is present, defibrillation should be attempted immediately. Then sodium bicarbonate should be administered. If an effective circulation is not restored after defibrillation and the initial dose of bicarbonate, a repeat dose of 1 mEq/kg should be given. It is recommended that, in hospitalized patients, further administration of sodium bicarbonate be governed by arterial blood gas and pH measurement.

Effective ventilation must accompany sodium bicarbonate administration to remove carbon dioxide in the arterial blood. Where blood gases and pH determinations are not available, one half of the initial dose may be administered at ten-minute intervals. Metabolic alkalosis and hyperosmolality from exces-

sive therapy must be avoided. Catecholamines may be given simultaneously or in rapid succession with sodium bicarbonate, but generally they should not be added to continuous infusions of the bicarbonate since this may cause inactivation of the catecholamines.

Sodium bicarbonate should not be used alone in cases of cardiac standstill or cases of persistent ventricular fibrillation. In these instances, repeated doses of epinephrine and sodium bicarbonate should be administered while continuing effective external cardiac compression and artificial ventilation. The combined use of epinephrine and sodium bicarbonate may result in a cardiac standstill converting into a ventricular fibrillation, which then can be defibrillated. Use of both drugs during ventricular fibrillation improves the status of the myocardium and enhances the effectiveness of the defibrillation.

Epinephrine.—Although epinephrine can be shown experimentally to produce ventricular fibrillation, its actions in restoring electrical activity in asystole and in enhancing defibrillation in ventricular fibrillation are well documented also. Epinephrine increases myocardial contractility, elevates perfusion pressure, lowers defibrillation threshold, and, in some instances, restores myocardial contractility in electromechanical dissociation. A dose of 0.5 ml of a 1:1,000 solution diluted to 10 ml, or 5 ml of a 1:10,000 solution, should be administered intravenously every five minutes during a resuscitation effort. Intracardiac administration may be utilized by personnel well trained in the technique if there has not been sufficient time to establish an intravenous route.

Atropine Sulfate.—Atropine sulfate reduces vagal tone, enhances atrioventricular conduction, and accelerates the cardiac rate in cases of sinus bradycardia. It is most useful in preventing arrest in profound sinus bradycardia secondary to myocardial infarction, particularly where hypotension is present. When there is profound bradycardia, acceleration of the heart rate to the normal rate of 60 to 80 beats per minute probably improves cardiac output and may reduce the incidence of ventricular fibrillation secondary to ectopic electrical activity.

Atropine sulfate is indicated for the treatment of sinus bradycardia with a pulse of less than 60 beats per minute when accompanied by premature ventricular contractions or systolic blood pressure of less than 90 mm Hg. It is also indicated for high degree atrioventricular block when accompanied by bradycardia. It is of no value in ventricular ectopic bradycardia in the absence of atrial activity. The recommended dose is 0.5 mg administered intravenously as a bolus, and repeated at five-minute intervals until a pulse rate greater than 60 is achieved. The total dose of atropine sulfate should not exceed 2 mg except in cases of third degree atrioventricular block, where larger doses may be required.

Lidocaine.—Lidocaine raises the fibrillation threshold and exerts its antidysrhythmic effect by increasing the electrical stimulation threshold of the ventricle during diastole. In usual therapeutic doses, there is no significant change in myocardial contractility, systemic arterial pressure, or absolute refractory period. This drug is particularly effective in depressing irritability where successful defibrillation repeatedly reverts to ventricular fibrillation. It also is particularly effective in the control of multifocal premature ventricular beats and episodes of ventricular tachycardia. Fifty to 100 mg should be administered slowly as a bolus intravenously and may be repeated if necessary. It may be followed by a continuous infusion of 1 to 3 mg/minute, usually not exceeding 4 mg/minute. Lidocaine, as 500 mg in 500 ml of 5% dextrose in water, provides a solution of 1 mg/ml for infusion. Lidocaine is of no value in asystole.

Morphine Sulfate.—Morphine sulfate is not indicated in cardiopulmonary resuscitation emergencies, but it is important in cases of myocardial infarction to relieve pain and in the treatment of pulmonary edema. For pain relief in acute myocardial infarction, 1 ml of morphine sulfate (15 mg) should be diluted to 5 ml (3 mg/ml). Of this solution, 1 ml (3 mg) to 1.5 ml (4.5 mg) should be given intravenously every 5 to 30 minutes as required. Experience has indicated that the titration of small doses at frequent intervals provides the desired effect and avoids significant respiratory depression.

Calcium Chloride.—Calcium chloride increases myocardial contractility, prolongs systole, and enhances ventricular excitability. Sinus impulse formation can be suppressed, and sudden death following a rapid intravenous injection of calcium chloride has been described, particularly in fully digitalized patients. Calcium chloride is useful in profound cardiovascular collapse (electromechanical dissociation). It may be useful in restoring an electrical rhythm in instances of asystole and may enhance electrical defibrillation.

The absolute dose of calcium required in cardiac arrest emergencies is difficult to determine and may vary widely. The usual recommended dose of calcium chloride is 2.5 ml to 5 ml of a 10% solution (3.4 to 6.8 mEq Ca^{++}). Where required, this amount should be injected intravenously as a bolus at intervals of ten minutes. Calcium gluconate provides less ionizable calcium per unit volume. If it is used, the dose should be 10 ml of a 10% solution (4.8 mEq). Calcium can also be administered as calcium gluceptate. The dose of this drug is 5 ml (4.5 mEq).

Repeated large doses of calcium may elevate calcium blood levels with a detrimental effect. Calcium must not be administered together with sodium bicarbonate since this mixture results in formation of a precipitate.

Alternate Drug Routes.—When prompt establishment of an intravenous lifeline is not possible, epinephrine (1 to 2 mg/10 ml sterile distilled water) or lidocaine (50 to 100 mg/10 ml sterile distilled water) can be effective when instilled directly into the tracheobronchial tree via an endotracheal tube. The endotracheal administration of other drugs for cardiopulmonary resuscitation has not yet been established.

Table 2.—Commonly Used Drugs for Infants and Children

Drug	Suggested Dose	Remarks
Epinephrine	Intracardiac—0.3 to 2 ml diluted 1:10,000 (0.1 ml/kg)	
Calcium chloride (10%)	I. V.—maximum dose of 1 ml/5 kg Intracardiac—1 ml/5 kg diluted 1:1 with saline	Use caution in digitalized children
Sodium bicarbonate	I. V.—1 ml (0.9 mEq)/kg diluted 1:1 with sterile water	Repeat dose after pH obtained and base deficit calculated
Levarterenol (Levophed) bitartrate	Infants: I. V.—1 mg in 500 ml of 5% D/W* Children: I. V.—2 mg/500 ml of 5% D/W	Titrate to desired effect Not to be used in endotoxic shock or renal shut-down
Metaraminol bitartrate (Aramine)	I. V.—25 mg/100 ml of 5% D/W	Titrate to desired effect
Mephentermine (Wyamine) sulfate	I. V.—0.05 mg	
Lidocaine (Xylocaine)	Infants: I. V.—0.5 mg/kg Children: I. V.—5 mg and repeat until desired effect I. V. Drip—6 mg/kg/4 hrs (100 mg in 500 ml of 5% D/W)	Not to exceed 100 mg/hr
Isoproterenol (Isuprel) hydrochloride	I. V. Drip—1 to 5 mg/500 ml of 5% D/W	Titrate to desired effect

*Dextrose in water.

Intramuscular atropine sulfate (2 mg) or lidocaine (300 mg) is effective in establishing therapeutic and prophylactic blood levels for dysrhythmia control, but this route requires the presence of adequate spontaneous circulation.

Useful Drugs

Vasoactive Drugs
- Levarterenol
- Metaraminol

Isoproterenol

Propranolol

Corticosteroids

Vasoactive Drugs (Levarterenol, Metaraminol).—The use of potent peripheral vasoconstrictors has been challenged by some authorities because of the possibility of reducing cerebral, cardiac, and renal blood flow. The choice of a vasoconstrictor or a positive inotropic agent remains controversial in the treatment of cardiac arrest and the immediate post-resuscitation period. However, during cardiac compression and the post-resuscitation period, blood pressure must be supported where low blood pressure and inadequate cerebral and renal perfusion give evidence of shock.

The selection of therapy is dictated by the patient's clinical state. In peripheral vascular collapse, manifested clinically by hypotension and the absence of significant peripheral vasoconstriction, intravenous levarterenol (Levophed) bitartrate in high concentrations of 16 μg/ml or metaraminol bitartrate (Aramine) in concentrations of 0.4 mg/ml of dextrose in water should be titrated intravenously. Metaraminol can be given intravenously as a bolus in a dose of 2 to 5 mg every five to ten minutes. Continuous administration is required to maintain a satisfactory blood pressure and adequate urinary output. These drugs are potent vasoconstrictors and have a positive inotropic effect on the myocardium. They are especially useful where systemic peripheral resistance is low.

Isoproterenol.—For patients with profound bradycardia demonstrated to be the result of complete heart block, isoproterenol (Isuprel) hydrochloride is the drug of choice for immediate treatment. It should be infused in amounts of 2 to 20 μg/minute (1 to 10 ml of a solution of 1 mg in 500 ml of 5% glucose in water) and adjusted to increase heart rate to approximately 60 beats per minute. It is useful also for profound sinus bradycardia refractory to atropine.

Propranolol.—The antiarrhythmic properties of the beta adrenergic blocking agents have proven useful in instances of repetitive ventricular tachycardia or repetitive ventricular fibrillation where maintenance of a rhythmic heartbeat cannot be achieved with lidocaine. The usual dose of propranolol is 1 mg intravenously. This may be repeated to a total of 3 mg under careful monitoring. Caution is required in patients with chronic obstructive pulmonary disease and cardiac failure.

Corticosteroids.—Present evidence favors the use of pharmacological doses of synthetic corticosteroids (5 mg/kg of methylprednisolone sodium succinate or 1 mg/kg of dexamethasone phosphate) for prompt treatment of cardiogenic shock or shock lung occurring as complications of cardiac arrest. Where cerebral edema is suspected following cardiac arrest methylprednisolone sodium succinate in doses of 60 to 100 mg every six hours may be beneficial. When pulmonary com-

plications such as a postaspiration pneumonitis is present, dexamethasone phosphate may be used in doses of 4 to 8 mg every six hours.

Postcardiac Arrest Drug Treatment.—In addition to corticosteroids, potent diuretic agents, hypothermia, and controlled hyperventilation may be useful for the prevention or attenuation of cerebral edema which may follow successful resuscitation. Potent diuretic agents (furosemide and ethacrynic acid) in doses of 40 to 200 mg may help to promote diuresis. Hyperosmolality may be aggravated by these agents.

Drug Dosage for Infants and Children.—The recommended drug dosages for infants and small children are listed in Table 2.

Stabilization of Patient's Condition for Transportation

Successful treatment is directly related to the rapidity with which a functional spontaneous rhythm can be restored. In cases of cardiac emergency outside the hospital, it is now clear that restoring adequate, spontaneous circulation at the scene is more likely to result in the victim's survival than the most skillfully continued basic life support measures during transportation. Every effort must be made to treat and stabilize the patient at the scene, since it is difficult to perform CPR effectively during transportation. Once the patient is stabilized, it is reasonable to transfer him to a life support unit.

Stabilization involves:

1. Assuring effective ventilation, either spontaneous or assisted.
2. Maintaining a stable cardiac rhythm and effective circulation, utilizing drugs as indicated.
3. Maintaining a functioning ECG monitor and an intravenous lifeline.
4. Establishing and maintaining communications necessary for consultation, transportation, and admission to a continuing care facility.

Termination of Basic or Advanced Life Support

The decision to terminate resuscitative efforts is a medical one (also see "Medicolegal Considerations") and depends upon an assessment by a physician of the cerebral and cardiovascular status of the patient. The best criteria of adequate cerebral circulation are the reaction of the pupils, the level of consciousness, movement, and spontaneous respiration. Deep unconsciousness, absence of spontaneous respiration, and pupils that are fixed and dilated for 15 to 30 minutes usually are indicative of cerebral death and further resuscitative efforts are generally futile. Cardiac death is likely when there is continuing absence of ventricular electrocardiographic activity after 10 minutes or more of adequate cardiopulmonary support including appropriate drug therapy. In children, or in unusual circumstances, eg, when the arrest is associated with hypothermia, resuscitative efforts should be continued for longer periods since recovery has been seen even after prolonged unconsciousness.

Part IV.—Life Support Units

A life support unit (LSU) is an integral part of a stratified system for cardiac care that is strategically located, properly identified, and has specific capability of rendering life support to patients with cardiopulmonary emergencies. Life support units can be either basic or advanced units. *Basic life support units* exist wherever there are individuals trained in CPR techniques and should be found at all patient care stations of hospitals, medical and dental offices, factories, public office buildings, and within homes and schools. *Advanced life support units*, in addition, must be able to monitor cardiac rhythms and treat cardiac dysrhythmias.

The Conference has set minimum standards for advanced life support units.

Standards for LSU'S

Structure and Access

The advanced life support unit must have accessible approaches and be clearly identified by conspicuous markers indicating the availability of emergency cardiac care. It must be equipped to communicate with appropriate emergency agencies as well as to provide basic and advanced life support. The logical sites for life support units are where cardiopulmonary emergencies reasonably can be anticipated, such as in hospitals and all areas where many people congregate.

In Hospitals

There should be triage for early symptoms and signs of heart attack in the hospital. The emergency department may be used to screen, monitor, and treat persons who arrive either on their own or by referral.

Every general hospital with acute care facilities should provide in its emergency department an advanced life support station so that any patient who has symptoms suspicious of myocardial infarction or other cardiopulmonary emergency will be placed immediately on monitoring and surveillance until a definite decision is made regarding his management. Cardiac monitoring always should precede any admin-

istrative details or medical history-taking.

If there is strong suspicion that the patient has an acute myocardial infarction, he should be transferred to a coronary care unit. It cannot be overemphasized that a patient with a history compatible with acute myocardial infarction should not be discharged from the emergency area merely because the initial electrocardiogram is normal. When the diagnosis is in doubt, it is always advisable to continue observation and monitoring. During transfer to the CCU by trained personnel, a patient should be connected to a battery-operated monitor-defibrillator and should be accompanied by appropriate drugs for administration en route if necessary.

Out of Hospitals

Sports Arenas, Convention Centers, Stadiums, Civic Auditoriums.—Areas where large numbers of people congregate, such as sports arenas, convention halls, stadiums, and auditoriums, should provide life support units. Once such a unit is established, it must be identified and a diagram of its location should be printed in the program and pre-program fliers and mailers.

The LSU should be located in a place with a high degree of visibility, such as near entrances or adjacent to exhibits that are known to be popular. Consideration should be given to proximity to major pedestrian traffic arteries and accessibility to all individuals. All personnel employed by the facility should know of the existence and location of the life support unit.

The unit should be identified by a sign reading "Emergency Life Support Unit," rather than "Emergency Aid Station," to emphasize the function of the unit. At the entry or registration area, a large sign should be provided to define the method of access to the LSU or to define what action to take if a life-threatening emergency occurs.

Where the physical layout lends itself to use of small mobile transport units, such as modified mobile carts, consideration should be given to a complete mobile system integrated with the LSU or with multiple LSU's.

The plan of action for an LSU in a public facility must include integration into the total emergency medical system.

Industrial Plants and Office Building Complexes.—In areas where a large number of people work, steps comparable to those for public facilities must be taken. A plan of action should be formulated as part of the total emergency medical system, including rapid access to the life support unit. In large complexes, LSU's are essential.

Areas With Large In-Transit Populations.—Airports and major railway terminals should provide similar LSU facilities with appropriate identification and easy access for travelers suffering life-threatening emergencies.

In addition, special provisions should be made for passengers aboard commercial aircraft. Airlines should provide passenger-carrying aircraft with standard kits of drugs (refer to "Essential Drugs" and "Useful Drugs") and syringes that can be made available to doctors with proper identification for in-flight treatment of cardiopulmonary emergencies. Oxygen, in cylinders with reducing valves capable of delivering up to 15 liters/minute for a period of 60 minutes (two E cylinders), should be available also. The cylinders, valves, and delivery equipment should be stored so that the oxygen may be delivered quickly to passengers anywhere in the aircraft.

The Conference recommends that the American Medical Association and all airlines request physicians to make their presence and availability known to the flight personnel prior to departure of the aircraft.

Capabilities of Advanced Life Support Units

An advanced life support unit must have certain capabilities with regard to availability, communication, and components. Advanced life support capability is to be provided within the confines of the LSU and to the entire physical complex which it serves, during the times required.

A faultless system of communication is essential to the effective delivery of advanced life support to persons in its area. This is to be correlated with responsible agencies (eg, security, administration) to ensure an effective flow of action for response.

The third capability an LSU must have concerns staff and equipment. Expert personnel, with all necessary equipment, must be available at all times in order to provide *advanced* life support by

1. Identifying patients with cardiopulmonary emergencies promptly.
2. Instituting immediate monitoring and establishing intravenous lifeline prior to obtaining a detailed medical and administrative history.
3. Providing continued surveillance until a professional decision on management is made.

In out-of-hospital LSU's, each unit must have the ability to stabilize the patient's condition prior to transfer to a continuing care facility. This necessitates providing a trained team with the appropriate portable equipment. The area's emergency medical system should allow personnel and equipment exchange to the transfer vehicle, effectively converting it to a mobile intensive care unit (MICU) to provide continuity of care until hospital admission is complete. In areas where MICU's are available, it is not necessary for the LSU team to leave its immediate vicinity. Basic life support always should be available, even when the life support unit team is occupied with transfer.

Personnel.—Persons capable of providing the quality and degree of care necessary for an LSU to operate in a rapid, efficient, and professional manner are essential. These units may be staffed by qualified

physicians, by specially trained nurses responding to standing orders, or by specifically trained allied health personnel who are authorized to perform this service. Each person staffing an LSU should be governed by a clear, written policy that defines his area of responsibility.

A physician knowledgeable and skilled in the management of basic and advanced cardiopulmonary emergencies must assume the medical responsibility for the unit. This responsibility includes direct or remote supervision under the physician's continuous or intermittent direction. Any physician who assumes responsibility for a patient in a LSU must be qualified to perform and administer advanced life support.

Nursing personnel must be familiar with and experienced in basic and advanced life support and must be able to direct lifesaving measures as well as provide a supporting role. In this regard, they should be familiar with the use of voice and ECG telemetry equipment if their station is so equipped.

Specialized continuing education programs for all LSU personnel are required to maintain an optimal level of proficiency and to acquaint personnel with new techniques and methods.

Emergency Medical Technicians (EMT's) must be trained at least to the level required for the training of ambulance personnel and others responsible for the prehospital phase of emergency cardiac care. Training programs must be hospital-affiliated and provide direct patient contact and care. A well-defined program additionally must include assisting in the care of the critically ill and injured patient, discussing cases, evaluating activities, and updating skills and knowledge on a regular basis. It is necessary that allied health personnel maintain their skills by continued periodic participation in hospital patient care and by demonstrating their proficiency on a set schedule. They must be able to function effectively without the physical presence of a physician or nurse, and, where provided, be totally competent to operate all equipment, including that necessary for communications and telemetry. Specialized continuing education programs for all LSU personnel are required to maintain an optimal level of proficiency and to acquaint personnel with new techniques and methods.

Equipment and Drugs.—The basic equipment and drugs necessary for an adequate advanced life support unit include those concerned with maintaining the airway and providing artificial ventilation and circulation.

Respiratory Management.—For airway management and artificial ventilation, the following equipment is necessary for all life support units:

Oxygen supply (two E cylinders) with reducing valves capable of delivering 15 liters/minute and with mask and reservoir bag
Oxygen reserve (two E cylinders)
Mask for mouth-to-mask ventilation
Oropharyngeal airways
S-tube (optional)
Laryngoscope with blades (curved and straight, for adult, child, and infant) and extra batteries and bulbs
Assorted adult-size (cuffed) and child-size (uncuffed) endotracheal tubes with stylet and 15 mm/22 mm adaptors
Syringe with clamp or plastic two-way or three-way valve for endotracheal tube cuffs
Acceptable bag-valve-mask, with provisions for 100% oxygen ventilation or a manually triggered (time-cycled) oxygen powered resuscitator
Suction (preferably portable), with catheters—sizes 6 to 16—and Yankauer-type suction tips
Nasogastric tube
Esophageal obturator airway (optional)
Cricothyrotomy set

Circulatory Management.—To provide adequate management of the circulatory system, the following equipment is essential for all advanced life support units:

Portable defibrillator-monitor with ECG electrode-defibrillator paddles or portable DC defibrillator and portable ECG monitor
Portable ECG machine, direct writing, with connection to monitor
Venous infusion sets (micro and regular)
Indwelling venous catheters (regular and special units):
Catheter outside needle (sizes 14 to 22)
Catheter inside needle (sizes 14 to 22)
Central venous pressure catheters
Intravenous solutions (5% dextrose in water, lactated Ringer's)
Cutdown set
Sterile gloves
Urinary catheters
Assorted syringes and needles, stopcocks, venous extension tubes
Intracardiac needles
Tourniquets, adhesive, disposable razor, and similar items
Thoracotomy tray

Essential Drugs.—All life support units must have these drugs available:

Sodium bicarbonate (prefilled syringes, 50 ml ampules, or 500 ml 5% bottles)
Epinephrine (prefilled syringes)
Atropine sulfate (prefilled syringes)
Lidocaine (Xylocaine [prefilled syringe])
Morphine sulfate
Calcium chloride

Useful Drugs.—These drugs are recommended for hospital and nonhospital life support units:

Aminophylline
Dexamethasone (Decadron)
Dextrose 50% (Ion-o-trate Dextrose 50%)
Digoxin (Lanoxin)
Diphenhydramine hydrochloride (Benadryl)
Ethacrynic acid
Furosemide (Lasix)
Isoproterenol (Isuprel) hydrochloride
Lanatoside C (Cedilanid)
Meperidine (Demerol) hydrochloride
Metaraminol bitartrate (Aramine)
Methylprednisolone sodium succinate (Solu-Medrol)
Nalorphine (n-allylnormorphine) hydrochloride
Levarternol (Levophed) bitartrate
Phenylephrine (Neo-synephrine) hydrochloride
Potassium chloride
Propranolol hydrochloride (Inderal)
Procainamide hydrochloride (Pronestyl)
Quinidine
Succinylcholine chloride
Tubocurarine chloride

Referral.—Each life support unit must have an established policy for referral. This policy should be

based on the knowledge of the medical capabilities for critical care in the vicinity and the ability of the individual LSU to communicate and consult with these facilities at all times. The patient should be referred to the most appropriate hospital. The LSU assumes full patient responsibility until safe transfer has been effected.

When the continuing care facility (hospital) provides both a coronary care unit and an emergency department, provisions should be made for the cardiac patient to enter the CCU directly, bypassing the emergency department. In some instances, however, further stabilization and specialized treatment may be necessary in the emergency department before transfer to the CCU.

Records.—A system of records must be developed and maintained throughout the course of each use of an LSU. The design must be such that a copy can be immediately available for the continuing care facility that assumes the eventual responsibility for the patient. There also must be a copy available for the long-term records of the LSU.

Communications.—At a minimum, the LSU must be able to communicate directly with the agency or persons who are bringing the patient to the unit and with the facility to which they transfer the patient for continuing care. It is recommended that the LSU also be in contact with the central coordinating and dispatching authority.

Standards for Mobile LSU'S

A mobile life support unit is a vehicle that has all the components, personnel, and capabilities of the LSU. Mobile life support units also can be categorized as basic or advanced, depending on the kind of life support they are equipped to provide. At a minimum, all ambulances should be capable of basic life support. Advanced mobile life support units should be able to rapidly transport necessary equipment and skilled personnel to a patient with a cardiopulmonary emergency and to render basic and advanced life support. This advanced mobile LSU may or may not transport the patient to a definitive care area. If not, it should be able to provide its life support capability in the form of personnel and portable equipment to some other transporting vehicle to effect safe transport after the patient has been stabilized.

Structure.—Mobile life support must be a part of a well-defined, community-wide plan for providing emergency medical services. The plan must integrate the mobile LSU's into an emergency cardiac care system containing fire departments, rescue teams, and ambulances, so that basic life support can be provided within four minutes from the emergency call. There should be a sufficient number and sufficient placement of mobile life support units to assure advanced life support to the patient within ten minutes or less.

Vehicle design for LSU's should be in relation to their role in the plan.[11] These vehicles may be only for transportation of equipment and personnel, or they may be for transportation of equipment, personnel, and patients. It is also necessary to provide central control, coordination, and a dispatching agency, with dispatchers trained in identifying the type of emergency and its precise geographic location.

All mobile LSU's must have sufficient trained personnel to provide two rescuers to remain with and administer to the needs of the patient throughout the emergency and until he is delivered to a continuing care facility.

Capabilities.—The mobile LSU's must be strategically deployed and have the capability for recognition, emergency treatment, and stabilization of cardiac patients. It is important that the patient be stabilized quickly at the site where the cardiopulmonary emergency occurred. Continuous monitoring of the patient by rescue personnel from the time of arrival of the mobile unit to the delivery of the patient to a LSU is a necessity. Communication with the base station, unit, and physician are desirable.

A mobile life support unit has some requirements that are different from those of a regular LSU. The mobile unit must possess the ability to develop and maintain appropriate, portable lifelines that will support ventilation and circulation continuously so that the patient may be transferred to the vehicle.

The training required for operation of regular life support units also must be augmented for personnel serving in the mobile life support unit. Training is needed in the areas of field operation of communications and telemetric equipment, vehicular guidance and defensive driving, local geography and traffic control, and how to interact with other agencies in situations such as establishing security and crowd control.

Components.—There are no differences between the components required for a mobile LSU and those for other LSU's regarding personnel, equipment, drugs, and records.

Additional mandatory features of the mobile LSU are specialized training of personnel, equipment that is portable and self-contained, special vehicle design, and a communications network.

Communications.—At a minimum, two-way voice communications with the central coordinating and dispatching authority and with the continuing care unit to which the patient will be delivered is necessary initially. The unit therefore must possess the capability of communicating with one or more continuing care facilities in order to give:

1. Notification of patient's expected time of arrival.
2. Notification of patient's condition.
3. Confirmation of acceptance by facility for continuing care.
4. Consultation regarding care.

As a later phase, there can be augmentation with physician's consultation and, when appropriate, ECG telemetry offers the advantage of remote monitoring and rhythm consultation, provided that medical consultation is on-line and a part of the system.

Part V.—Medicolegal Considerations and Recommendations

The Conference wishes to make clear that, unless otherwise provided, nothing in these standards is intended to limit or inhibit persons, either inside or outside of health care facilities, from providing emergency medical treatment. Emergency care should always be provided in life-threatening situations. In addition, unless otherwise indicated, these standards are universally applicable. In cases involving techniques of basic and advanced life support, minimum requirements for appropriate action have been defined. In areas of policy, recommendations have been made, and it is intended that these recommendations will become reflective of actual practice.

It is appreciated that full implementation of these standards will place an enormous burden on the personnel and facilities of agencies, organizations, and institutions that are or will be involved in emergency care, as well as those agencies, organizations, and institutions responsible for training and certification. Since it may be unrealistic to expect immediate compliance with these standards in some circumstances, a reasonable time for implementation should be allowed.

Initiation and Termination of Resuscitation Efforts

Physicians.—Physicians have an obligation to initiate CPR in any instance in which it is medically indicated. When the victim of cardiac arrest is not the patient of the physician, a unique relationship is created that may be described as the Good Samaritan–victim relationship.

The physician should continue basic life support measures until one of the following occurs:

1. The patient's personal physician takes charge,
2. He has reasonable assurance that the victim will continue to receive properly performed basic and/or advanced life support by properly trained and designated professional personnel, or
3. The patient recovers or is pronounced dead.

Nonphysicians.—Nonphysicians should initiate CPR according to the standards of the American Heart Association and to the best of their knowledge and capability in cases they recognize as cardiac arrest. They should not be held liable for failure to initiate CPR if such decision is consistent with current standards.

The nonphysician who initiates basic or advanced life support should continue his resuscitation efforts until one of the following occurs:

1. Effective spontaneous circulation and ventilation have been restored,
2. Resuscitation efforts have been transferred to another responsible person who continues basic life support,
3. A physician or a physician-directed individual or team assumes responsibility,
4. The victim is transferred to properly trained and designated professional medical or allied health personnel charged with responsibilities for emergency medical services, or
5. The rescuer is exhausted and unable to continue resuscitation.

Orders Not to Resuscitate

The purpose of cardiopulmonary resuscitation is the prevention of sudden, unexpected death. Cardiopulmonary resuscitation is not indicated in certain situations, such as in cases of terminal irreversible illness where death is not unexpected or where prolonged cardiac arrest dictates the futility of resuscitation efforts. Resuscitation in these circumstances may represent a positive violation of an individual's right to die with dignity. When CPR is considered to be contraindicated for hospital patients, it is appropriate to indicate this in the patient's progress notes. It also is appropriate to indicate this on the physician's order sheet for the benefit of nurses and other personnel who may be called upon to initiate or participate in cardiopulmonary resuscitation.

Conference Recommendations for Advanced Life Support

1. Every hospital must have a written plan and a mechanism for advanced life support consistent with available personnel, equipment, and facilities, and available throughout the installation on a 24-hour-per-day basis. This plan should be tested regularly and should be reviewed annually by the responsible hospital CPR/ECC committee.

2. Lack of CPR certification should not, per se, prevent administration of advanced life support by properly trained medical, nursing, and allied health personnel in an emergency situation.

Conference Recommendations on Necessary Legislative Action

1. It is recommended that state legislation be clarified to allow professional allied health personnel who

are rendering emergency care outside of the hospital and are certified in advanced life support to function with maximum effectiveness. Such legislation must provide specifically that individuals certified in advanced life support be permitted to function when a physician is not present, provided, however, that such certified person is under the general supervision of a physician. General supervision is defined as direct or remote supervision by continuous or intermittent communication with a licensed physician to assure physician involvement in decisions requiring such involvement. This requirement for supervision by a physician shall not be interpreted to mean that such life-saving procedures as cardiac defibrillation, appropriate drug therapy, and other measures should ever be withheld when the circumstances demand such action according to the training standards for emergency medical technicians functioning in this capacity.

2. It is recommended that all hospital and other acute care facility staff and employees who are involved in direct patient care in any capacity must be certified in basic life support and should have knowledge of and be involved in the CPR plan of that facility.

3. It is recommended that all county, state, and national medical organizations make serious and concerted efforts to (*a*) clarify the Medical Practice Act in their state in terms of its application to persons rendering basic and advanced life support and (*b*) establish an official mechanism to approve CPR courses given in accordance with American Heart Association standards and by instructors certified according to American Heart Association standards.

4. It is recommended that national certification be established to ensure that those trained in basic life support and advanced life support have had appropriate training according to American Heart Association standards and are proficient in the application of that training.

5. It is recommended that qualified immunity (ie, for acts done in good faith and not involving gross negligence or willful, wanton, or reckless misconduct) be provided for those certified in basic or advanced life support.

6. It is recommended that a declaration of the immunity provided by common law for lay persons who either have not been certified or have not been trained in basic life support should be prepared and publicized widely.

7. It is recommended that immunity from civil liability for certified instructors and associations that are involved in instruction in accordance with the American Heart Association standards should be provided.

8. It is recommended that all policemen, firemen, and other first-line responders be trained and certified in basic life support as a necessary and indispensable job requirement. All professional emergency department personnel should have adequate training and certification in basic and advanced life support.

9. It must be established and properly promulgated that policemen and any law enforcement official, or any individual functioning in a similar capacity, have an affirmative obligation (*a*) to defer to a person more qualified than themselves in the delivery of basic life support and (*b*) not to interfere in an ongoing effort at stabilization of an individual receiving basic life support until a reasonable, mutually agreeable decision is made by that individual and the rescuer that transportation or other appropriate measures in the delivery of care be initiated.

Conference Recommendations on Implementation of Standards

To assure maximum effectiveness, the Conference recommends that its standards, as contained in this statement, be adopted and implemented by the following agencies and organizations:

1. The Joint Commission on Accreditation of Hospitals, insofar as they apply to hospitals.
2. State regulatory bodies for promulgation of standards and recommendations.
3. Professional medical and allied health associations, for the purpose of issuing statements jointly or individually for maximum dissemination of these standards, to ensure uniformity in their application and to protect both those who act in accordance with them and the emergency victim.
4. The American Heart Association, in taking all necessary steps to disseminate these standards broadly, including appropriate programs, training materials, and publications, and by seeking support for such dissemination from appropriate foundations, federal agencies, medical organizations, and other sources.
5. The American National Red Cross and other life-saving agencies, charged with the responsibility of providing adequate training to nonprofessional rescuers and the general public.
6. All government health care services and facilities.
7. Other responsible agencies and organizations, including medical, dental, and nursing schools; airlines; industry; and sports centers.

It is further recommended that this statement be given the widest possible publication, republication, and distribution in its complete form, or in its individual parts, provided proper procedures are followed.

References

American Heart Association (AHA)

1. *Emergency Resuscitation Team Manual: A Hospital Plan.* New York: AHA, 1968. (EM439)
2. *Emergency Measures in Cardiopulmonary Resuscitation* (Revised). New York: AHA, 1969. (EM376A)
3. *Definitive Therapy in Cardiopulmonary Resuscitation* (Revised). New York: AHA, 1971: (EM377A)
4. *Cardiopulmonary Resuscitation: A Manual for Instructors.* New York: AHA, 1967. (EM408)
5. *Training of Ambulance Personnel in Cardiopulmonary Resuscitation.* New York: AHA, 1965: (EM386A)
6. *The Dentist's Role in Cardiopulmonary Resuscitation.* New York: AHA, 1968. (EM407A)
7. *Training of Lifeguards in Cardiopulmonary Resuscitation.* New York: AHA, 1970. (EM438A)

National Academy of Sciences–National Research Council (NAS–NRC)

8. Cardiopulmonary Resuscitation: Statement by the Ad Hoc Committee on Cardiopulmonary Resuscitation of the Division of Medical Sciences, National Academy of Sciences–National Research Council. *JAMA*, 198:372-379, 1966.

9. "Accidental Death and Disability: The Neglected Disease of Modern Society," Committee on Trauma and Committee on Shock, Division of Medical Sciences. Washington, DC: NAS-NRC, September 1966.

10. *Cardiopulmonary Resuscitation: Conference Proceedings*, May 23, 1966. Washington, DC: NAS-NRC, 1967. (Publication 1494)

11. "Medical Requirements for Ambulance Design and Equipment." Committee on Emergency Medical Services, Division of Medical Sciences, Washington, DC: NAS-NRC, September 1968. (Publication USGPO 1970 0-381-725)

12. "Ambulance Design Criteria." Committee on Ambulance Design Criteria of the Highway Research Board, Division of Engineering. Washington, DC: NAS-NRC, June 1969.

13. *Training of Ambulance Personnel and Others Responsible for Emergency Care of the Sick and Injured at the Scene and During Transportation*. Committee on Emergency Medical Services, Division of Medical Sciences. Washington, DC: NAS-NRC, March 1968. (Publication USGPO 1970 0-381-726)

14. "Advanced Training Program for Emergency Medical Technician-Ambulance." Committee on Emergency Medical Services, Division of Medical Sciences. Washington, DC: NAS-NRC, September 1970.

15. "Roles and Resources of Federal Agencies in Support of Comprehensive Emergency Medical Services." Division of Medical Sciences, Washington, DC: NAS-NRC, March 1972.

Inter-Society Commission for Heart Disease Resources

16. Cardiovascular disease—Acute care. *Circulation* 43:A97-A133, January 1971.

17. Resources for the management of emergencies in hypertension. *Circulation* 43:A157-A160, March 1971.

18. Resources for the acute care of peripheral vascular diseases. *Circulation* 43:A161-A169, April 1971.

19. Resources for the optimal care of patients with acute myocardial infarction. *Circulation* 43:A171-A183, May 1971.

20. Resources for the optimal care of acute respiratory failure. *Circulation* 43:A185-A195, June 1971.

21. Electronic equipment in critical care areas. Part II. The electrical environment. *Circulation* 44:A237-A246, October 1971.

22. Critical performance criteria-defibrillators. Instrumentation Study Group. *Circulation* 47:A359-A361, June 1973.

Other Government Agencies

23. US Department of Transportation, National Highway Safety Bureau. "Basic Training Program for Emergency Medical Technician-Ambulance: Concepts and Recommendations," 1969. (Publication USGPO 1970 0-372-388).

24. US Department of Transportation, National Highway Safety Bureau. "Basic Training Program for Emergency Medical Technician-Ambulance: Course Guide and Course Coordinator Orientation Program," 1969. (Publication USGPO 1970 0-372-389).

25. US Department of Transportation, National Highway Safety Bureau. "Basic Training Program for Emergency Medical Technician-Ambulance: Instructor's Lesson Plans," 1969. (Publication USGPO, Catalogue No. TD 2.208:EM 3/3, 1969).

26. US Department of Transportation, National Highway Traffic Safety Administration: "Communications-Guidelines for Emergency Medical Services." Washington: Government Printing Office, 1972.

27. US Department of Health, Education and Welfare, Health Services and Mental Health Administration. "Emergency Medical Services Communication Systems," August 1972. (DHEW Publication No. HSM 73-2003).

28. US Department of Health, Education, and Welfare. Public Health Service. "Compendium of State Statutes on the Regulation of Ambulance Services, Operation of Emergency Vehicles, and Good Samaritan Laws." Health Services and Mental Health Administration, Division of Emergency Health Services (Revised), 1969. (Publication USGPO 1969-0-353-618).

29. US Department of Health, Education, and Welfare. Public Health Service. "Emergency Health Services Selected Bibliography." Health Services and Mental Health Administration, Division of Emergency Health Services, 1970. (Publication USGPO 1970, 0-354-043).

Professional Medical Societies

30. American College of Surgeons Committee on Trauma. A curriculum for training emergency medical technicians. *Bull Am Coll Surgeons* 54:273-276, 1969.

31. American College of Surgeons. Committee on Trauma. Essential equipment for ambulances. *Bull Am Coll Surgeons* 55: 7-13, 1970.

32. American Academy of Orthopaedic Surgeons. Emergency Care and Transportation of the Sick and Injured, by the Committee on Injuries. Chicago: AAOS, 1971.

33. American Medical Association. Commission on Emergency Medical Sevices. Developing Emergency Medical Services: Guidelines for Community Councils. Chicago: AMA, 1973.

34. American Society of Anesthesiologists. Community-wide emergency medical services: Recommendations by the Committee on Acute Medicine of the American Society of Anesthesiologists. *JAMA* 204:595-602, 1968.

Private Groups

35. Manually operated resuscitators. *Health Devices* 1:13-17, April 1971.

36. Inspection of defibrillators. *Health Devices* 1:109-113, August 1971.

37. Battery-operated defibrillator/monitors. *Health Devices* 2: 87-103; February 1973.

38. Line-operated synchronized defibrillators. *Health Devices* 2:117-129, March 1973.

39. External Cardiac compressors. *Health Devices* 2:136-151, April 1973.

Individuals

40. Yu PN: Pre-hospital care of acute myocardial infarction. *Circulation* 45:189-204, 1972.

41. Don Michael TA, Gordon AS: Esophageal obturator airway: A new adjunct for artificial ventilation. Proceedings, National Conference on Standards for CPR and ECC, NAS-NRC, Washington, DC, to be published.

Sources of References

A. American Heart Association, Committee on Cardiopulmonary Resuscitation and Emergency Cardiac Care, 44 E 23rd St, New York 10010. Also available from affiliates. (References 1-8, 39)

B. Division of Medical Sciences, National Academy of Sciences-National Research Council, 2101 Constitution Ave, Washington, DC 20418. (References 8-9, 11, 14-15)

C. Information Clearinghouse, Division of Emergency Health Services, Health Services and Mental Health Administration, 5600 Fishers Lane, Rockville, MD 20852. (References 9, 13-14, 27)

D. American Medical Association, Commission on Emergency Medical Services, 535 N Dearborn St, Chicago 60610. (References 8-9, 33)

E. Printing and Publishing Office, National Academy of Sciences, 2101 Constitution Ave, Washington, DC 20418. (Reference 10)

F. Superintendent of Documents, US Government Printing Office, Washington, DC 20402. (References 11-13, 23-26, 28-29)

G. Inter-Society Commission for Heart Disease Resources, 44 E 23rd St, New York 10010. (References 16-22)

H. American College of Surgeons, 55 E Erie St, Chicago 60611. (References 30-31)

I. American Academy of Orthopaedic Surgeons, 430 N Michigan Ave, Chicago 60611. (Reference 32)

J. American Society of Anesthesiologists, Committee on Acute Medicine, 515 Busse Hwy, Park Ridge, IL 60068. (Reference 34)

K. Emergency Care Research Institute, 913 Walnut St, Philadelphia 19107. (References 35-39)

Appendix

Participants at National Conference
Washington, DC

Panel Members

Panel I: Basic Life Support

Chairman: Archer S. Gordon, MD
Cochairman: Joel J. Nobel, MD

Berkebile, P.	Don Michael, T. A.	Mongeon, E.
Bienvenu, O. J.	Eberhart, C. M.	Oswald, R.
Bosserman, H.	Elam, J. O.	Owen, W. D.
Brummitt, W. M.	Hampton, A.	Resnikov, L.
Burnap, T. K.	Hendryson, I. E.	Russell, C. W.
Campbell, J.	Johnson, J.	Safar, P.
Dail, C. P.	Jude, J. R.	Schowalter, E. J.
Del Guercio, L. R. M.	Kaplan, B. H.	Stephenson, H.
Dick, W.	Lund, I.	Thiessen, A. W.

Panel II: Advanced Life Support

Chairman: Arnold Sladen, MD
Cochairman: Donald H. Dembo, MD

Alvarez, H.	De Leo, B. C.	Pyfer, H.
Benson, D.	Goldberg, A.	Rattenborg, C.
Berenyi, K.	Kaplan, B.	Sarnoff, S.
Burleson, J.	Kent, K.	Semler, H.
Crul, J.	Knickerbocker, G. G.	Weil, M. H.

Panel III: Medicolegal Aspects of CPR and ECC

Chairman: Kevin M. McIntyre, MD
Cochairman: Robert D. Huber, JD

Bernzweig, E.	Coombs, J.	Jessiman, A. G.
Carter, W.	Dalen, J. E.	Reed, B. C.
Chayet, N.	Gibbs, R.	Sagall, E. L.

Panel IV: Emergency Cardiac Care (ECC) Systems

Chairman: Leonard Scherlis, MD
Cochairman: Malcolm R. Parker, MD

Ailshie, G.	Griffiths, A. H.	Pantridge, J. F.
Baker, R.	Herman, L.	Parker, S.
Carveth, S.	Hill, L.	Romano, T.
Cobb, L. A.	Jorde, A.	Rose, B.
Crampton, R. S.	Lambrew, C.	Rose, L.
Duggan, J. J.	Lewis, A. J.	Sergant, S.
Easley, R.	Lewis, R. P.	Simmons, R.
Edlevich, S.	McDermott, S.	Swanson, L. W.
Esposito, G.	McMahon, M.	Wagner, P.
Gallo, R.	Nagel, E. L.	Whipple, G. H.
Gold, S.	Nolte, C.	
Graf, W. S.	Oscherwitz, M.	

National Organizations Represented

Ambulance Association of America
American Academy of Orthopaedic Surgeons
American Academy of Pediatrics
American Association of Inhalation Therapists
American Association of Physician Assistants
American College of Cardiology
American College of Chest Physicians
American College of Emergency Physicians
American College of Physicians
American College of Sports Medicine
American Heart Association
American Hospital Association
American Medical Association
American National Red Cross
American Society of Anesthesiologists
American Thoracic Society
Boy Scouts of America
Canadian Heart Foundation
Canadian Red Cross
Emergency Care Research Institute
International Association of Fire Chiefs
National Association of Underwater Instructors
National Emergency Department Nurses Association
National Research Council-National Academy of Sciences
National Surf Life Saving Association of America
Royal Life-Saving Society of Canada
Society for Critical Care Medicine
US Department of the Army
  Office of the Surgeon General
  Walter Reed Army Institute of Research
US Department of Defense-
    Defense Civil Preparedness Agency
US Department of Health, Education and Welfare
  US Public Health Service
    Health Services and Mental Health Administration
    Division of Emergency Medical Services
    National Heart and Lung Institute
    National Institutes of Health
    Regional Medical Programs Service
US Department of the Navy
  US Naval Hospital
  National Naval Medical Center
US Department of Transportation-National Highway
    Traffic Safety Administration
US Veterans Administration
White House-Assistant Physician to the President
Young Men's Christian Association

American Heart Association Affiliates and Chapters Represented

Alabama Heart Association
Arizona Heart Association
California Heart Association
  Central Valley Heart Association
  Long Beach Heart Association
  Sacramento-Yolo-Sierra Heart Association
  San Francisco Heart Association
Chicago Heart Association
Colorado Heart Association
Connecticut Heart Association
  Heart Association of Central Connecticut, Inc.
  Heart Association of Greater Hartford
  Heart Association of Greater New Haven
Delaware Heart Association
Washington, DC, Heart Association

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association.
Learn and Live.sm

Transthoracic resistance in human defibrillation. Influence of body weight, chest size, serial shocks, paddle size and paddle contact pressure

RE Kerber, J Grayzel, R Hoyt, M Marcus and J Kennedy

Circulation 1981;63;676-682
Circulation is published by the American Heart Association. 7272 Greenville Avenue, Dallas, TX 72514
 Print ISSN: 0009-7322. Online ISSN: 1524-4539

Transthoracic Resistance in Human Defibrillation

Influence of Body Weight, Chest Size, Serial Shocks, Paddle Size and Paddle Contact Pressure

RICHARD E. KERBER, M.D., JOSEPH GRAYZEL, M.D., ROBERT HOYT, B.S., MELVIN MARCUS, M.D., AND JEFFREY KENNEDY, B.S.

SUMMARY Successful defibrillation depends on delivery of adequate electrical current to the heart; one of the major determinants of current flow is transthoracic resistance (TTR). To study the factors influencing TTR, we prospectively collected data from 44 patients undergoing emergency defibrillation. Shocks of 94–450 J delivered energy were administered from specially calibrated Datascope defibrillators that displayed peak current flow, thereby permitting determination of TTR. Shocks were applied from standard (8.5-cm diameter) or large (13 cm) paddles placed anteriorly and laterally. First-shock TTR ranged from 15–143 Ω. There was a weak correlation between TTR and body weight ($r = 0.45, p < 0.05$) and a stronger correlation between TTR and chest width ($r = 0.80, p < 0.01$). Twenty-three patients who were defibrillated using standard 8.5-cm paddles had a mean TTR of 67 ± 36 Ω (± SD), whereas 21 patients who received shocks using paddle pairs with at least one large (13 cm) paddle had a 21% lower TTR of 53 ± 24 Ω ($p = 0.05$, unpaired t test). Ten patients received first and second shocks at the same energy level; TTR declined only 8%, from 52 ± 19 to 48 ± 16 Ω ($p < 0.01$, paired t test). In closed-chest dogs, shocks were administered using a spring apparatus that regulated paddle contact pressure against the thorax. Firmer contact pressure caused TTR to decrease 25%, from 48 ± 22 to 36 ± 17 Ω ($p < 0.01$, paired t test). Thus, human TTR varies widely and is related most closely to chest size. TTR declines only slightly with a second shock at the same energy level. More substantial reductions in TTR and increases in current flow can be achieved by using large paddles and applying firm paddle contact pressure.

THE ELECTRICAL DOSE required for human defibrillation remains controversial.[1] Although dose is usually quantified by the delivered energy, it is the electrical current flow between the paddles that actually depolarizes a critical amount of myocardium and terminates ventricular fibrillation.[2] Current flow is determined not only by the energy selected, but also by the transthoracic resistance (TTR). In a patient with unusually high TTR, current flow might be inadequate for defibrillation. It would be important to reduce transthoracic resistance if possible. Animal studies have suggested that TTR can be reduced by using large defibrillator paddles and a low-resistance interface between paddles and skin.[3, 4] However, neither the range nor the determinants of TTR have been adequately evaluated in human defibrillation.

In patients undergoing emergency defibrillation, we undertook a prospective investigation of several potentially important factors influencing TTR: body weight, chest size, chest wall thickness, paddle size and the effects of repeated shocks of the same energy level. Another possible determinant of TTR, paddle contact pressure, was studied in shocks applied to animals.

From the Cardiovascular Center and the Department of Internal Medicine, University of Iowa Hospital, Iowa City, Iowa.

Supported in part by NHLBI grant HL-014388 and by a grant from the Datascope Corporation.

Dr. Grayzel's address: 262 Fountain Road, Englewood, New Jersey.

Address for correspondence: Richard E. Kerber, M.D., Department of Medicine, University of Iowa Hospital, Iowa City, Iowa 52242.

Received August 26, 1979; revision accepted July 23, 1980.
Circulation 63, No. 3, 1981.

Methods

All defibrillations were performed using Datascope MD2J damped sinusoidal wave form defibrillators. In this defibrillator, when an energy level is selected the energy that will be delivered into a 50-Ω resistance is displayed; if any charge leaks off, the display indicates the decline. Thus, at the moment the defibrillator was fired, the exact amount of delivered energy was displayed and recorded. After discharge, the peak current (in amperes) that flowed between the paddles was displayed and recorded.

To permit calculation of TTR, each defibrillator was charged to energy settings ranging from 75–460 J, and at each energy level was fired into dummy resistances ranging from 15–150 Ω. The resultant peak current flow for each firing was noted and current vs resistance calibration curves were plotted for each energy level (fig. 1). Thus, knowing the defibrillator used, the energy displayed before firing and the current that resulted permitted us to determine a patient's TTR from each defibrillator's calibration curve.

To evaluate the effect of paddle size on TTR, we equipped, at random, some defibrillators with two standard 8.5-cm-diameter paddles and others with one standard 8.5-cm and one specially constructed 13-cm-diameter paddle, and yet others with two 13-cm paddles. Paddles were coated with Hewlett-Packard Redux paste, a low-resistance interface between paddle and skin,[3] and placed so that the anterior (positive) paddle was centered over the upper right parasternal area and the lateral (negative) paddle was over the cardiac apex. When paddle pairs of unequal size were used, the smaller paddle was always placed over the

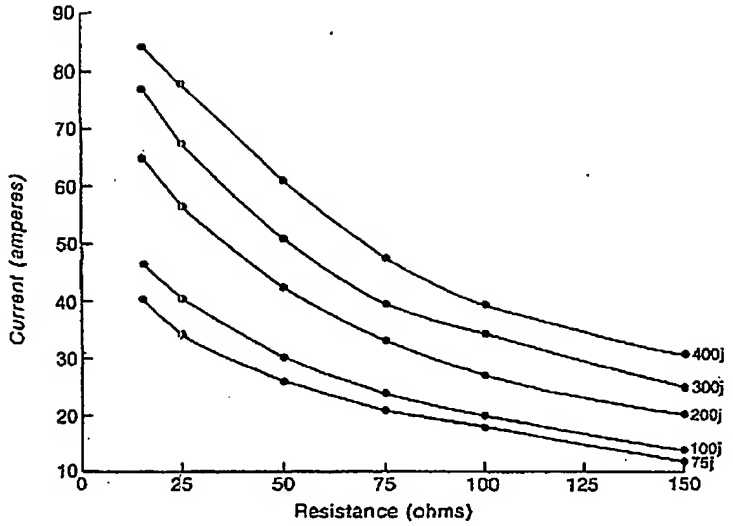


FIGURE 1. *Typical calibration curves for the Datascope MD2J defibrillator, showing peak current flow vs transthoracic resistance at various energy levels. This family of curves was constructed for each defibrillator used by firing the defibrillator into dummy resistances. Knowing the energy displayed before firing and the resultant peak current allowed determination of the patient's transthoracic resistance from such curves.*

cardiac apex. Anteroposterior paddle placement was not used in any patient.

Using a protocol approved by the Human Research Committee of the University of Iowa, we prospectively collected data on 44 patients undergoing emergency defibrillation. Body weights ranged from 20–159 kg (mean 72 kg). The clinical diagnoses of the patients varied widely. Half the patients were known to have cardiac disease: chronic ischemic heart disease (10 patients), acute myocardial infarction (eight patients), valvular heart disease (three patients) and congestive cardiomyopathy (one patient). Fourteen patients had primarily noncardiac disorders, including sepsis (three patients), severe diabetes (two patients), pulmonary embolism (two patients), cerebral vascular accident (two patients), renal failure (one patient), lymphoma (one patient), metastatic carcinoma (one patient), severe lung disease with CO_2 retention (one patient), and chronic osteomyelitis (one patient). In eight patients defibrillated on or shortly after admission to the hospital, insufficient information was available to establish a diagnosis. Physicians administering shocks were advised to select an initial energy dose of 2 J/kg body weight, which would result in an initial shock of 150–200 J for the average adult, a dose shown by others to be effective in most patients.[1] If the first shock failed to defibrillate, the shock was repeated using a dose of 4 J/kg, then 6 J/kg. This protocol was followed in most cases; some patients received several shocks at the same energy dose, which ranged from 100–400 J. In all cases, delivered energy was displayed before firing, and peak current after firing was recorded and used to calculate TTR.

The effects of paddle contact pressure were studied in closed-chest dogs anaesthetized with chloralose-urethane and ventilated mechanically. Contact pressure was assessed in four dogs by designing a paddle-holding apparatus that enabled the operator to adjust the tension of a spring scale connecting the paddle levers and thereby to select paddle contact pressure against the thorax. We estimated light contact pressure with hand-held paddles to be the equivalent of 10 N of tension in the paddle-holding apparatus. Firm pressure was estimated to be equivalent to 50 N of tension, equivalent to a fivefold increase in effective contact pressure. Values of peak current obtained at these tensions were similar to currents obtained in preliminary animal studies that used lightly and firmly applied hand-held paddles. The paddles were coated with Redux paste, mounted in the holding apparatus and applied to a shaved chest. In additional studies in three of these dogs, no paste was used and bare paddles were applied to the shaved skin. Shocks were synchronized to the R wave of the ECG in these dogs and delivered when the lungs were at peak inspiration. Light and firm pressure shocks were given in random order using 8.5-cm or 13-cm paddles and a 20- or 40-J energy dose.

We reasoned that TTR might be related to the physical separation between the paddles, and that this would in turn be related to chest width (i.e., lateral chest diameter), as anterolateral paddle placement was used, and possibly also to the thickness of the chest wall tissues. Therefore, we reviewed chest x-rays, which were available in 29 patients. On the posteroanterior films, we measured the maximal chest width between outermost skin folds. From the lateral chest x-rays (available in 20 patients), we measured the distance between the anterior skin and the manubrium-sternum junction (i.e., anterior chest wall thickness in the region where the anterior paddle was placed).

Statistical Analysis

Linear regression analysis was performed to determine the relationship between first-shock TTR and body weight and that between TTR and the chest x-ray measurements. To determine the effects of pad-

TABLE 1. *Correlations Between Transthoracic Resistance and Its Potential Determinants*

Determinant	Paddle size	n	r	p	Slope	Intercept
Body weight	All sizes	44	0.28	NS	—	—
	Standard*	21	0.46	< 0.05	0.57	29
	Large†	23	0.15	NS	—	—
Chest width	All sizes	29	0.52	< 0.05	3.4	−71
	Standard	14	0.80	< 0.01	5.5	−131
	Large	15	0.51	< 0.05	3.4	−84
Chest wall thickness	All sizes	20	0.45	< 0.05	11.4	25
	Standard	8	0.27	NS	—	—
	Large	12	0.50	< 0.05	14	17

*Two 8.5-cm-diameter paddles.
†Two 13-cm-diameter paddles or one 13-cm and one 8.5-cm paddle.

dle size on TTR, we used an unpaired t test to compare the group shocked with two 8.5-cm paddles and the group shocked with one or two 13.5-cm paddles. We used the paired t test to compare the effect of repeated same-energy shocks in patients and the effects of variable paddle contact pressure on TTR in dogs. All results are reported as mean ± SD.

Results

Range of TTR and Correlation with Potential Determinants (table 1)

The mean first-shock TTR for the whole group ranged from 15–143 Ω (mean 60 ± 31 Ω).

TTR and Body Weight

There was no correlation between TTR and body weight for the group as a whole ($r = 0.28, p$ = NS) or for subgroups of patients who received first shocks at the same energy level. Because TTR is affected by paddle size (see below), we also performed linear regression analysis of subgroups of patients who received shocks from standard paddles only and from one or two large paddles. There was a significant but weak correlation between TTR and body weight ($r = 0.45, p < 0.05$) for the group of patients shocked with two standard-size paddles. Three of 21 patients who received shocks from standard paddles weighed more than 90 kg, as did six of 23 patients who received shocks from large paddles (p = NS).

TTR and Chest Size

Comparison of the TTR values of the entire group with the chest x-ray measurements showed statistically significant but weak correlations between TTR and chest width ($r = 0.52, p < 0.05$) and chest wall thickness ($r = 0.45, p < 0.05$). Separating the patients into two groups based on paddle size substantially improved the correlation with chest width ($r = 0.80$, $p < 0.01$) in patients shocked with two standard paddles (fig. 2).

TTR and Paddle Size

Figure 3 shows first-shock delivered energy and TTR using two standard (8.5 cm) paddles (n = 21) compared with that using one or two large (13 cm) paddles (n = 23). The mean delivered energy received by the two groups was virtually identical: 226 ± 94 J (standard paddles) vs 230 ± 104 J (one or two large paddles). However, the transthoracic resistance of the patients receiving shocks from one or two large paddles was 21% lower: 67 ± 36 Ω (range 16–143 Ω) using standard paddles vs 53 ± 24 Ω (range 15–132 Ω) using large paddles ($p = 0.05$).

We also subdivided the large-paddle group into patients who received shocks from one large and one

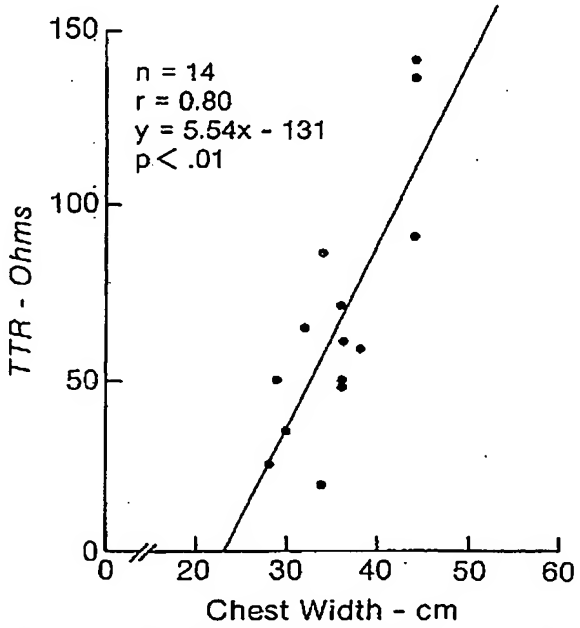


FIGURE 2. *Transthoracic resistance (TTR) vs chest width. A good correlation between these two variables is present for patients shocked with standard size paddles.*

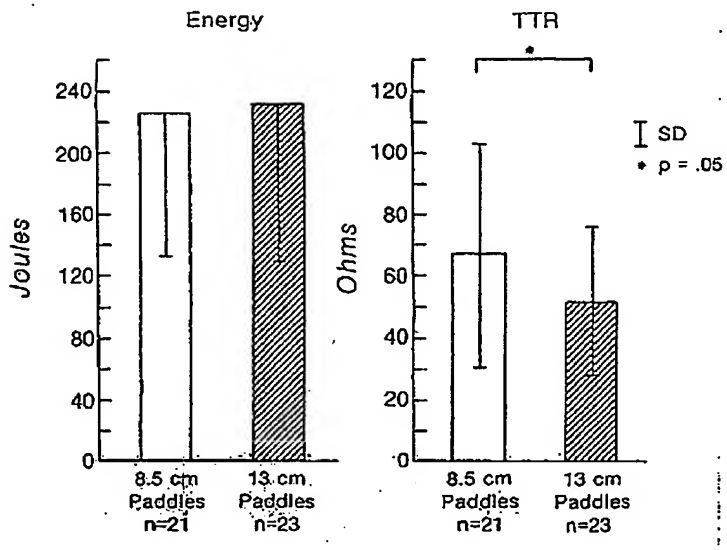


FIGURE 3. *Effect of paddle size on transthoracic resistance (TTR). Both groups received shocks of similar energy levels, but the patients shocked with one or two large paddles had significantly lower TTR (paired t test). 8.5 cm paddles = two standard size paddles; 13 cm paddles = two large paddles or one large and one standard paddle.*

standard paddle (nine patients) and those who were shocked with two large paddles (14 patients). The mean delivered energy of the one large/one standard paddle group was 199 ± 88 J vs 255 ± 109 J for the two large paddle group (p = NS). The corresponding TTRs were 47 ± 19 Ω vs 56 ± 26 Ω (p = NS).

Effect of Repeated Same-energy Shocks on TTR

Ten patients received their first two shocks at the same energy level, which ranged from 100–400 J. The mean energy for both shocks was 235 ± 91 J. Figure 4 plots the TTR and peak current of these two shocks. TTR declined only 8%, from 52 ± 19 to 48 ± 16 Ω ($p < 0.01$); peak current increased only 4%, from 46 ± 16 to 48 ± 16 A ($p < 0.01$). TTR showed no decrease and therefore current flow showed no increase with the second shock in three of these 10 patients.

Effect of Paddle Contact Pressure on TTR

Shocks using light and firm paddle pressures (in random order) were delivered to nonfibrillating dogs using 8.5-cm paddles coated with Redux paste and a 40-J energy dose (2 J/kg body weight). Light paddle contact pressure resulted in a TTR of 48 ± 22 Ω whereas with firm contact pressure TTR was 25% lower, 36 ± 17 Ω ($p < 0.01$) (fig. 5). Peak current flow was 21 ± 8 A with low contact pressure and 23 ± 6 A with firm pressure ($p < 0.01$), a 10% increase (fig. 5). Using large (13 cm) paddles and a lower energy dose (20 J), low contact pressure resulted in a TTR of 42 ± 4 Ω and a peak current flow of 15 ± 1 A. Firm contact pressure resulted in a TTR of 29 ± 1 Ω ($p < 0.01$), a 31% lower value, and a peak current flow of 18 ± 0 A ($p < 0.01$), a 16% increase. Similar decreases in TTR and increases in peak current occurred with firm pressure even when bare paddles were applied to the shaved skin. With 8.5-cm paddles and a 40-J energy dose, TTR decreased from 95 ± 15 to 60 ± 6 Ω ($p < 0.05$) as contact pressure was increased from light to firm. Peak current flow increased from 14 ± 1 to 18 ± 1 A ($p < 0.05$).

Discussion

The main findings of this investigation are (1) the range of TTR in humans is very wide; (2) TTR is weakly related to body weight and more strongly to chest width; (3) TTR is lowered and current flow in-

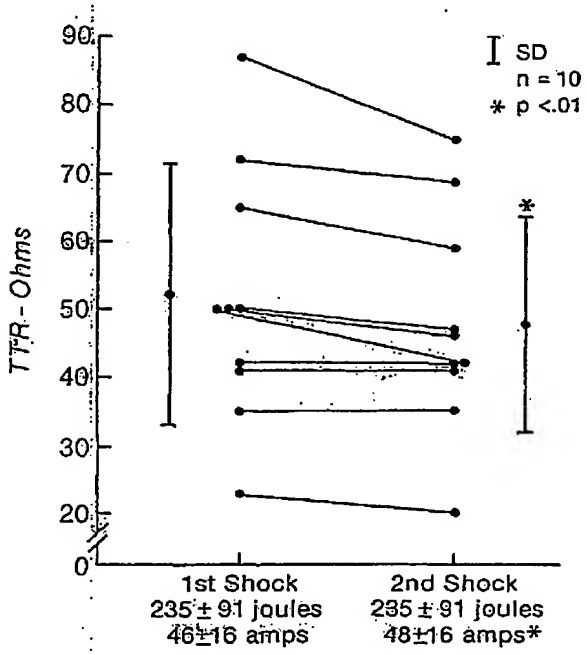


FIGURE 4. *Effect of same-energy shocks on transthoracic resistance (TTR). A second shock at the same energy level resulted in a significant but small decline in TTR and an increase in peak current flow.*

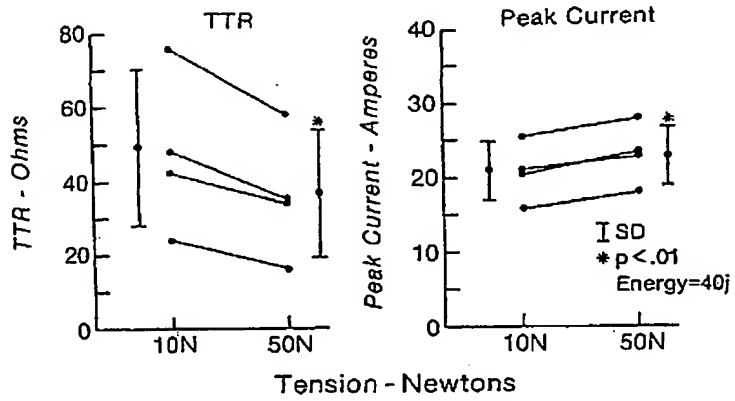


FIGURE 5. *Effects of paddle contact pressure in dogs. Firmer paddle contact pressure against the thorax (higher tension in the spring apparatus) resulted in a significant decrease in transthoracic resistance (TTR) and an increase in peak current flow.*

creased by using paddles larger than those generally manufactured; (4) TTR is lowered and current flow increased by applying paddles firmly to the chest; (5) although TTR is lower during a second shock of the same energy as the first, this decline and the resultant increase in current flow are very small and of questionable clinical significance.

Tacker and co-workers, in animal and human studies,[5-7] found that the energy and current necessary to defibrillate were directly related to body weight and that heavy subjects required higher energies. These investigators suggested that presently available defibrillators may provide inadequate energy and current to defibrillate some heavy patients, and called for the construction of more powerful units. Other workers have vigorously disagreed, finding that present defibrillators are adequate to defibrillate virtually all patients, including heavy ones.[8-10] Assuming that some heavier patients may need higher energies to defibrillate, one possible mechanism consistent with the studies of Tacker et al.,[5-7] is that heavy subjects have higher TTR. Our data show that TTR is weakly related to body weight. However, TTR is more clearly related to chest width, a relationship also noted by Ewy et al.,[11] who studied patients undergoing elective cardioversion with anteroposterior paddles and found a similar relationship ($r = 0.82$) between TTR and anteroposterior chest diameter. If the energy selected is low and therefore marginal for defibrillation,[8] a high TRR might result in inadequate current flow and failure to defibrillate a heavy, big-chested subject.

Although the threshold current for human defibrillation has not been established, we have noted successful defibrillation with peak current flow as low as 0.21 A/kg body weight.[12] Patton and Pantridge[13] found that the mean current required to defibrillate was 0.35 A/kg. Using the latter figure, a 100-kg subject would require a peak current flow of 35 A to defibrillate. Figure 1 shows that a defibrillator capable of delivering 400 J would generate more than 35 A of current across the chest if the transthoracic resistance were less than 130 Ω, which was the case in 41 of our 44 patients. Three patients in our study had TTR greater than 130 Ω; their body weights were 80, 90 and 159 kg. The presumptive current requirements for defibrillation in these three patients, using a threshold of 0.35 A/kg, would be 28 A, 32 A and 56 A. A 400-J defibrillator would generate adequate current to defibrillate the first two of these heavy patients, but would fall short of the current necessary to defibrillate the heaviest patient, who had a TTR of 137 Ω. This theoretical analysis is in agreement with published data[8-10] indicating that in most patients the widely available 400-J maximal energy defibrillators are adequate, but it suggests that in an occasional very large patient, the current flow from such defibrillators may be insufficient. Because TTR can be decreased by use of large paddles and firm contact pressure, such maneuvers might be of critical importance in a very large patient with high TTR.

In a preliminary communication of ours in 1978,[14] the relationship between TTR and body weight failed to achieve statistical significance. That report was based on 23 patients and is superseded by the expanded number of 44 patients we report now, where the relationships between TTR and body weight and TTR and chest size proved to be statistically significant.

A transthoracic resistance of 50 Ω is assumed when reporting the delivered energy of shocks.[15] Although this figure is useful for standardization of defibrillators, it is a great oversimplification if used to estimate the anticipated current flow, as the range of TTR we encountered varied eightfold, from 15–143 Ω, and averaged 67 Ω for 8.5-cm paddles. Because even the best relationship between TTR and its determinants was only $r = 0.80$ (TTR vs chest width), it is very difficult to estimate accurately how much current will actually flow from the first shock.

Previous studies comparing 13-cm paddles with 8-cm paddles in shocks applied to nonfibrillating anaesthetized dogs, as well as studies of elective cardioversion in humans, showed a lower TTR with large paddles.[4, 16] Our study extends these observations to patients undergoing emergency defibrillation. At any given energy level, use of larger paddles will lower TTR, increase current flow and improve the likelihood of achieving defibrillation. This would be especially important in cases where the current flow is marginal for successful defibrillation, perhaps because

of high TTR. The less concentrated current path resulting from use of large paddles probably also reduces the likelihood of causing myocardial necrosis at higher energy levels.[17] However, overly large paddles could result in a substantial portion of the total current flow traversing extracardiac paths within the thorax, missing the heart and thereby reducing the proportion of current available for defibrillation.[18] Animal studies in our laboratory have shown that *intracardiac* current in 20-kg dogs is increased by using 13-cm rather than 8.5-cm paddles.[19] Moreover, Thomas et al.[20] found that 12.8-cm paddles were more effective than 8-cm paddles in canine defibrillation. Because the human heart is larger than the dog heart, it seems probable that 13-cm paddles would result in increased intracardiac current and improved defibrillation success in humans also. Although this study does not establish the ideal paddle size in humans, it suggests that paddles larger than those presently manufactured should be used.

Although firm paddle contact pressure is advised in defibrillation,[21] an experimental basis for this recommendation has been lacking. This study shows that firm pressure is indeed beneficial because it reduces TTR and increases current flow. It appears that a substantial proportion of total TTR is at the paddle-skin interface. Firm mechanical contact pressure probably reduces TTR by increasing the number of low-resistance electrical contact points between the paddle surface and the skin. A more uniform dispersion of the electrode paste may also occur with higher contact pressure, but firm contact pressure reduced TTR even when bare paddles were used.

Factors of paddle size and paddle contact pressure appear to be additive in reducing TTR. In the same dogs, standard-size paddles applied with light contact pressure yielded a mean TTR of 48 Ω, whereas large paddles applied firmly reduced TTR to 29 Ω. Thus, increasing both paddle size and contact pressure resulted in a combined TTR decline of 40%.

Studies in experimental animals[22, 23] and in patients undergoing elective cardioversion[24] suggested that TTR decreases with repeated shocks at the same energy level. This phenomenon was most evident between the first and second shocks. Chambers et al.[24] suggested that this may explain why electrical conversion from ventricular fibrillation can occur after an initial failure at the same energy level. Although we confirmed that TTR in emergency defibrillation does decrease with a second same-energy shock, the magnitude of this decline was small, and the resultant increase in peak current flow was only 4%. This increment is unlikely to be meaningful in the clinical setting. A substantial increase in current flow can be obtained more reliably and quickly by selecting a higher energy for a second defibrillation attempt. For example, in the 10 patients who received a second shock at the same energy level as the first (235 ± 91 J), the current increased only 4%, from 46 ± 16 to 48 ± 16 A ($p < 0.01$). In contrast, in another nine patients, the delivered energy was increased by 100 J for a second shock, from 231 ± 52 to 329 ± 54 J. This resulted in a 25% increase in current flow, from 50 ± 14 to 62 ± 14 A ($p < 0.001$, paired t test).

In this report, we included data from shocks whether or not the shocks were successful in terminating ventricular fibrillation. Defibrillation success is influenced by many factors. In addition to adequate current passing through the heart, other factors that have been proposed as influencing defibrillation success include the duration of ventricular fibrillation,[8, 25] metabolic abnormalities[25] and the cardiac diagnosis and state of the myocardium.[8, 10, 26] Thus, although reducing TTR and increasing current flow should improve the chances of successful defibrillation, this single factor is only one of several determinants.

We conclude that in human defibrillation TTR varies widely and is best related to chest size. TTR can be substantially reduced and peak current flow increased during defibrillation by using large paddles and firm paddle contact pressure. These maneuvers will maximize current flow from presently available defibrillators. However, repeating an initially unsuccessful shock at the same energy level causes only minimal changes in TTR and peak current. Therefore, an initially unsuccessful shock should be quickly followed by a second shock at a higher energy level to increase current flow substantially and avoid delays in achieving defibrillation.

References

1. Lown B, Crampton RS, DeSilva RA, Gascho J: The energy for ventricular defibrillation — too little or too much? N Engl J Med 298: 1252, 1978
2. Zipes DP, Fischer J, King RM, Nicoll A de B, Jolly WW: Termination of ventricular fibrillation in dogs by depolarizing a critical amount of myocardium. Am J Cardiol 36: 37, 1975
3. Ewy GA, Tapen D: Impedance to transthoracic direct current discharge: a model for testing interface material. Med Instrum 12: 47, 1978
4. Ewy G: Defibrillator paddle electrodes. *In* Proceedings of the Cardiac Defibrillation Conference, West Lafayette, Indiana, Purdue University, 1975, pp 39–44
5. Tacker WA, Galioto TM, Giuliani E, Geddes LA, McNamara G: Energy dosage for human trans-chest electrical ventricular defibrillation. N Engl J Med 210: 214, 1974
6. Geddes LA, Tacker WA, Rosborough JP, Moore AG, Cabler PS: Electrical dose for ventricular defibrillation of large and small subjects using precordial electrodes. J Clin Invest 53: 310, 1974
7. Collins RE, Giuliani ER, Tacker WA, Geddes LA: Transthoracic ventricular defibrillation: success and body weight. (abstr) Med Instrum 12: 53, 1978
8. Campbell NPS, Webb SW, Adgey AAJ, Pantridge JF: Transthoracic ventricular defibrillation in adults. Br Med J 2: 1379, 1977
9. Gascho JA, Crampton RS, Sipes JN, Cherwek ML, Hunter FP, O'Brien WM: Energy levels and patient weight in ventricular defibrillation. JAMA 242: 1380, 1979
10. Gascho JA, Crampton RS, Cherwek ML, Sipes JN, Hunter FP, O'Brien WM: Determinants of ventricular defibrillation in adults. Circulation 60: 231, 1979
11. Ewy GA, Ewy MD, Silverman J: Determinants of human transthoracic resistance to direct current discharge. (abstr) Circulation 46 (suppl II): II-150, 1972
12. Kerber RE, Grayzel J, Gascho J, Kennedy J, Hoyt R: What are the current requirements for human defibrillation? (abstr) Med Instrum 14: 56, 1980
13. Patton JN, Pantridge JF: Current required for ventricular

defibrillation. Br Med J 1: 513, 1979
14. Kerber R, Hoyt R: Human transthoracic resistance in emergency defibrillation: range and relationship to body weight. (abstr) Circulation 57 (suppl II): II-204, 1978
15. Standards for Cardiopulmonary Resuscitation and Emergency Cardiac Care. JAMA 227: 837, 1974
16. Connell PN, Ewy GA, Dahl CF, Ewy MD: Transthoracic impedance to defibrillator discharge. Effect of electrode size and electrode-chest wall interface. J Electrocardiol 6: 313, 1973
17. Dahl CF, Ewy GA, Warner ED, Thomas ED: Myocardial necrosis from direct current countershock. Effect of paddle electrode size and time interval between discharges. Circulation 50: 956, 1974
18. Ewy GA: Effectiveness of direct current defibrillation: role of paddle electrode size: II. (letter) Am Heart J 93: 674, 1977
19. Hoyt R, Grayzel J, Kerber R: Intracardiac current in defibrillation. Effect of paddle size. (abstr) Circulation 59 (suppl II): II-192, 1979
20. Thomas ED, Ewy GA, Dahl CF, Ewy MD: Effectiveness of direct current defibrillation: role of paddle electrode size. Am Heart J 93: 463, 1977
21. Parker MR: Defibrillation and synchronized cardioversion. *In* Advanced Cardiac Life Support. Dallas, American Heart Association, 1975
22. Geddes LA, Tacker WA, Cabler DP, Chapman K, Rivera BS, Idder H: Decrease in transthoracic resistance during successive ventricular defibrillation trials. Med Instrum 9: 179, 1975
23. Dahl CF, Ewy GA, Ewy MD, Thomas ED: Transthoracic impedance to direct current discharge: effect of repeated countershocks. Med Instrum 10: 151, 1976
24. Chambers W, Miles R, Stratbucker R: Human chest resistance during successive countershocks. (abstr) Circulation 56 (suppl III): III-183, 1977
25. Kerber RE, Sarnat W: Factors influencing the success of ventricular defibrillation. Circulation 60: 226, 1979
26. Tacker WA, Geddes LA, Cabler PS, Moore AG: Electrical threshold for defibrillation of canine ventricles following myocardial infarction. Am Heart J 88: 476, 1974

Oral Prostaglandin E_2 in Ductus-dependent Pulmonary Circulation

ERIC D. SILOVE, M.D., J. YASHU COE, M.B., M. F. SHIU, M.D., JANE D. BRUNT, B.Sc., ANTONY J. F. PAGE, M.B., SHYAM P. SINGH, M.B., AND MURRAY D. MITCHELL, M.A., D. PHIL.

SUMMARY Prostaglandin E_2 (PGE_2) was administered orally, in doses of 12–65 μg/kg at intervals of 1–4 hours, to 12 neonates in whom the pulmonary circulation depended on patency of the ductus arteriosus. After an oral dose, both oxygen saturation (Sao_2) and plasma PGE_2 concentration increased consistently within 15–30 minutes, reaching values comparable to those during i.v. infusions. Treatment continued for 5 days to 4 months. In eight infants, PGE_2 withdrawal resulted in a decrease of Sao_2, from a mean of 75 ± 7% to 57 ± 10% (± SD).

The ductus remained responsive for long periods — in four infants, for over 3 months. Consequently, surgery could be delayed until the infants and their pulmonary arteries had grown. Side effects during oral therapy were similar to those during i.v. infusion but were less severe in this series. The effectiveness and simplicity of oral PGE_2 administration have advantages over i.v. administration, especially for long-term treatment.

INFUSIONS of the E-type prostaglandins are widely used to maintain patency of the ductus arteriosus in neonates with severely reduced pulmonary blood flow.[1-7] Therapy usually continues for hours or days; the longest reported course of i.v. therapy has been 29 days in one infant.[7] We have briefly described the efficacy of long-term oral prostaglandin E_2 (PGE_2)[8-10] and now report our experience of oral therapy in 12 patients. In particular, we tested (1) whether oral PGE_2 consistently maintained ductus patency; (2) whether oral PGE_2 could easily be substituted for i.v. therapy; (3) the requirements of dosage and frequency of administration; and (4) whether the ductus remained PGE_2-dependent after a period of months.

Patients and Methods

This study was approved by the Research Ethical Committees of both the Children's Hospital and the Central Birmingham Health District. Informed parental consent was obtained in each case.

Twelve infants with severely diminished pulmonary blood flow were treated with oral PGE_2. Their mean weight was 2.90 kg. The clinical features are given in table 1. In patients 2, 3, 4, 6, 11 and 12, the surgeons considered the pulmonary arteries, as shown by angiography, to be too small to attempt a shunt operation. We hoped that prolonged treatment would encourage growth. In patients 1 and 7, PGE_2 therapy was restarted after failure of a palliative operation.

From the Department of Pediatric Cardiology, Children's Hospital, Ladywood Middleway, Birmingham, and Nuffield Department of Obstetrics and Gynaecology, University of Oxford, John Radcliffe Hospital, Oxford, England.

Presented in part at the 52nd Scientific Sessions of the American Heart Association, Anaheim, California, November 1979.

Dr. Mitchell is a Medical Research Council Senior Research Fellow.

Address for correspondence: Dr. E. D. Silove, Children's Hospital, Lady Middleway, Birmingham B16 8ET, England.

Received October 9, 1979; revision accepted July 11, 1980.
Circulation 63, No. 3, 1981.